IN THE UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF MISSISSIPPI WESTERN DIVISION

ANNIE CHATMAN Plaintiff

V. CASE NO. 5:11-CV-69-DCB-JMR

PFIZER, INC.; WYETH, LLC; SCHWARZ PHARMA, INC.; PLIVA, INC.; RANBAXY PHARMACEUTICALS, INC; TEVA PHARMACEUTICALS USA, INC.; BARR PHARMACEUTICALS, LLC

Defendants

MEMORANDUM OPINION AND ORDER

Plaintiff Annie Chatman brings suit in this Court pursuant to 28 U.S.C. § 1332 against Defendants Pfizer, Inc., Wyeth LLC, and Schwarz Pharma, Inc. N/K/A UCB, Inc., manufacturers of the brandname drug Reglan (collectively, Brand Defendants), and Defendants Pliva, Inc., Barr Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., manufacturers of Reglan's generic equivalent, metoclopramide (collectively, Generic Defendants). The First Amended Complaint [docket no. 55] alleges that, after taking metoclopramide, Chatman developed tardive dyskinesia, an irreversible neurological disorder characterized by repetitive and involuntary bodily movements, and states various state law claims against the Defendants. The Generic Defendants have moved for judgment on the pleadings pursuant to Rule 12(c) [docket no. 70] and the Brand Defendants have moved for summary judgment pursuant to Rule 56 [docket no. 72]. Having carefully considered the Motions, the Plaintiff's opposition thereto, applicable statutory and case law, and being otherwise fully advised in the premises, the Court finds that Generic

Defendants' Motion to Dismiss is granted and Brand Defendants' Motion for Summary Judgment is granted in part and denied in part.

I. SUMMARY OF THE ARGUMENTS

Any difficulty these Motions present is not with the relevant facts, which are few and, for the present purposes, undisputed. Rather, the difficulty these Motions present is in resolving the question of whether either group of Defendants can be liable for causing Chatman's neurological disorder.

In 2007, Chatman's physician prescribed either Reglan or its generic equivalent metoclopramide to treat her gastroesophageal reflux disease (GERD). Two years after taking the generic drug, Chatman was diagnosed with tardive dyskinesia. Am. Compl. ¶ 23, docket no. 55; Pl.'s Pharm. Records, docket no. 72-3; Pl.'s Schwarz Prod. Id., docket no. Stipulation of 72-5; Stipulation of Wyeth Prod. Id., docket no. 72-6. The Generic Defendants argue that they cannot be liable for Chatman's injuries because all her causes of action are pre-empted by federal law. To reach this conclusion, they first contend, correctly, that the Supreme Court held in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), that federal law pre-empts failure-to-warn claims against a generic drug manufacturer, and therefore they cannot be liable for Chatman's failure-to-warn claim. But they seek to extend the application of this holding by arguing that all Chatman's claims, regardless of whether they are characterized as strict liability or gross negligence claims, are in essence claims for their failure to warn of the dangers of taking their drug. As the Generic Defendants explain in their briefs, the majority of courts, applying different states' tort laws, have adopted this basic view.

Following on the heels of this argument are the Brand Defendants, who concede that federal law would not pre-empt a failure-to-warn claim against them, see Wyeth v. Levine, 555 U.S. 555 (2009), but argue that the facts only support a failure-to-warn claim against the Generic Defendants because Chatman has admitted that she took the generic drug. They too cite case after case which holds that a brand-name drug manufacturer cannot be liable for the harms caused by its failure to warn of the dangers of taking a drug that it did not manufacture. They further contend that no alternative common-law theory of liability exists under which they could be liable for harms caused by a product that they did not make. In the end, the message of both groups of Defendants is the same: it may be unfortunate for Chatman, but the FDA has dealt her a losing hand. Mensing, 131 S. Ct. at 2581.

II. ANALYSIS

A. Generic Defendants' Motion for Judgment on the Pleadings

1. Standard of review for a Rule 12(c) motion

The Generic Defendants' Rule 12(c) motion is evaluated under the familiar 12(b)(6) standard. <u>Jebaco, Inc. V. Harrah's Operating</u>
Co., 587 F.3d 314, 318 (5th Cir. 2009). In considering a motion

under Rule 12(b)(6), the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff."

Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit, 369 F.3d 464, 467 (5th Cir. 2004) (quoting Jones v. Greninger, 188 F.3d 322, 324 (5th Cir. 1999)). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

To overcome a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. "Factual allegations 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 555 (citations and footnote omitted). "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." Iqbal, 556 U.S. at 678.

2. The Parties dispute the impact of Mensing

While the Generic Defendants overstate their position with the assertion "Mensing mandates dismissal of the lawsuit," the Supreme

Court's holding in that case is the obvious starting point. In Mensing, two plaintiffs separately brought suits in the Eighth and Fifth Circuits, alleging, like Chatman, that they developed tardive dyskinesia after taking metoclopramide. Mensing, 131 S. Ct. at 2572. The cases were consolidated on appeal to the Supreme Court, which was asked to determine "whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, [the plaintiffs' failure-to-warn claims]." Id. The answer to this question turned on whether the generic manufacturers could unilaterally alter metoclopramide's labeling, i.e., the warning given to the plaintiffs, through the various mechanisms provided by the FDA rules and regulations. The Supreme Court held that it is impossible under the FDA's regulatory scheme for a generic manufacturer to unilaterally alter its drug's labeling because the regulations require a generic drug to have the

 $^{^{1}}$ The Supreme Court made clear that the plaintiffs' claims had been reduced to one failure-to-warn theory by the time it reached the Supreme Court. Id. at 2573.

² The terms "labeling" and "label" are used throughout this opinion. 21 C.F.R. § 1.3 defines these terms as follows:

⁽a) Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

⁽b) Label means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

same composition and labeling as that of its brand-name counterpart. Id. at 2575-78. Since Reglan's labeling was deemed insufficient by the plaintiffs, see id. at 2574, the Supreme Court concluded that it was impossible for the metoclopramide manufacturers to strengthen their labeling in such a way as to comply with the state-mandated duty to warn of the dangers of its use. Id. at 2578-79. Therefore, the plaintiffs' failure-to-warn claims were found to be implicitly pre-empted by federal law. Id. at 2581.

In the present case, Chatman has pleaded the following claims against the Generic Defendants: negligence (Count I); breach of (Count II); warranties (Count liability III); misrepresentation, suppression of the evidence, and fraud (Count IV); and gross negligence (Count V). Even Chatman agrees that to the extent that these claims against the Generic Defendants fall within Mensing's holding, her claims are also pre-empted. Pl.'s Resp. Br. at 7. The debate between the Parties is (1) whether Mensing forecloses her failure-to-warn claim, even though she has alleged that the Generic Defendants did not communicate to her the FDAapproved 2003 and 2004 labeling changes, and (2) whether Mensing forecloses all of her remaining causes of action against the Generic Defendants because they are, at base, failure-to-warn claims. The Court will address each of these issues in turn.

3. Whether <u>Mensing</u> forecloses Chatman's failure-to-warn claim even though she has alleged that the Generic Defendants failed to update their labeling to comply with the 2003 and 2004 FDA-approved labeling changes

As to Chatman's first so-called attempt to "plead around Mensing," Chatman asserts in her brief that the 2002 labeling for metoclopramide in the Physicians' Desk Reference (PDR)-the reference book on which the prescribing doctor may have relied-did not account for Reglan's FDA-approved 2003 and 2004 labeling changes, which respectively warned of the dangers the drug posed to geriatric consumers and the dangers of long-term use. Chatman argues that the Generic Defendants³ could have complied with the duties imposed upon them by state law by mailing letters to prescribing doctors to inform them of the heightened FDA-approved warnings. The Generic Defendants counter that: (1) the plaintiffs in Mensing were in an identical position and yet the Supreme Court found their claims were pre-empted; (2) the Mensing Court determined that the plaintiffs could not send the "Dear Doctor" letters described by Chatman; (3) Chatman alleges in her Amended Complaint that her physician relied on the Reglan warnings, not the PDR; (4) even if they could have sent Dear Doctor letters, according to Chatman's Amended Complaint, these warnings would not have prevented the harm she suffered as a result of taking their drug.

³ As the Court understands it, Pliva's, Barr's, and possibly Teva's package inserts included pre-2003 labeling. Gen. Defs.' Reply at 2 n.2.

The Fifth Circuit recently repudiated Chatman's failure-to-update argument in an unpublished opinion. See Morris v. PLIVA, Inc., 2013 WL 563506, at *2 (5th Cir. Feb. 14, 2013). Interpreting Mensing, the Fifth Circuit explained that not only does the Hatch-Waxman Act's "same as" requirement apply to the content of the labeling, but it also applies to how the labeling is communicated. Id. In other words, a generic manufacturer can only communicate the same information communicated by the brand-name manufacturer. Id. In her Amended Complaint, Chatman alleges that both the Brand Defendants and the Generic Defendants failed to update their labeling to match the stronger 2003 and 2004 FDA-approved labeling. Am. Compl. ¶ 113(m). Because she alleges that the Brand Defendants did not "take the lead" in communicating the stronger 2003 and 2004 warnings, see id., she may not maintain her failure-to-update argument against the Generic Defendants.

⁴ Additionally, the Generic Defendants indicate that there are other problems with Chatman's failure-to-update theory. First, Chatman at times alleges that the 2003 and 2004 warnings, had they been incorporated into the metoclopramide labeling, would not have prevented her injuries. Thus, it would have been impossible for the Generic Defendants to comply with their state-mandated duty to warn even if they could have communicated the heightened warnings to Chatman. See Morris, 2013 WL 563506, at *2. Further, the Defendants suggest that Chatman admits that she did not rely on the package inserts. See Gen. Defs.' Reply at 6. The Court does not read Chatman's Amended Complaint in such a restrictive manner, see Am. Compl. ¶ 25, but it acknowledges that her Amended Complaint advances inconsistent theories. This type of pleading is not fatal, however. See Fed. R. Civ. P. 8(d)(2) ("If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient.").

4. Whether <u>Mensing</u> forecloses each of Chatman's remaining causes of action against the Generic Defendants because they are at base failure-to-warn claims

The more hotly disputed issue is whether Chatman's other claims against the Generic Defendants can be either reduced to a failure-to-warn claim or should be dismissed on other grounds. Specifically, the Generic Defendants argue that Mensing, Mississippi law, and Chatman's own pleadings work against the survival of each of her state-law claims. As the Generic Defendants recognize, the national consensus is that Chatman's other claims are poorly camouflaged failure-to-warn claims, and therefore most courts have rebuffed plaintiffs' attempts to recover under alternative state-law theories of liability including negligence and fraud. Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 187 (5th Cir. 2012) (per curiam) (citing cases). If Chatman's remaining claims are disguised failure-to-warn claims, then they are unquestionably subject to Mensing's preemption analysis.

After analyzing this question under Mississippi law, at least two trial courts in Mississippi have joined the national consensus, granting the generic drug manufacturers' motion to dismiss in a situation almost factually indistinguishable from Chatman's. See generally, Gardley-Starks v. Pfizer, Inc., --- F. Supp. 2d ----, 2013 WL 139900 (N.D. Miss. Jan. 10, 2013); Lashley v. Pfizer, Inc., 877 F. Supp. 2d 466 (S.D. Miss. 2012). And even more recently, the Fifth Circuit clearly indicated its view in the final Demahy

opinion, which is that <u>Mensing</u>'s holding would apply to all statelaw claims against the Generic Defendants, regardless of how those claims are characterized. Demahy, 702 F.3d at 187.

a. Chatman's products liability claims

The Mississippi Product Liability Act (MPLA), Miss. Code Ann. § 11-1-63, is the exclusive remedy for Chatman's strict liability claims against the Generic Defendants. Lawson v. Honeywell Int'l, Inc., 75 So. 3d 1024, 1027 (Miss. 2011). This statute has a failure-to-warn, defective-design, and breach-of-express-warranty component. Miss. Code Ann. § 11-1-63(a)(i)2-(i)(4). The Court has already addressed Chatman's failure-to-warn claim above and therefore focuses on her two remaining products liability theories. The Generic Defendants argue that Chatman has failed to properly plead these alternative theories, but if the Court disagrees, they alternatively argue that these claims are also foreclosed by Mensing.

Having carefully considered Chatman's Count II, which is something of an amalgamation of each of Mississippi's strict liability theories, the Court concludes that Chatman has not successfully pleaded a design-defect claim. To start, for this theory to be successful, Chatman must not only identify the defect in the design but also allege that a viable alternative design exists. See Miss. Code Ann. § 11-1-63(f)(ii). Regardless of how liberally her Amended Complaint is construed, Chatman has done

neither and, for this reason alone, she has not properly pleaded a true design-defect claim. Instead, what Chatman clearly and consistently alleges is that the drug's "defect" is in the information which did and did not accompany the drug, including warnings about the drug's extended use, the dangers posed to geriatric patients, and the possibility of developing tardive dyskensia. These allegations can only relate to the drug's labeling and thus are allegations that make up a failure-to-warn claim. The same is true of Chatman's breach-of-express-warranty claim, which is likewise premised entirely on the "factual representations" regarding the drug's use (in other words, the labeling). See Miss. Code Ann. § 11-1-63(a)(i)4. There can be no doubt that Chatman's statutory claims are based on the inadequacy of the warning she was given, and therefore these claims are subject to Mensing and thus fall within the analysis above.

b. Chatman's common-law claims

As for Chatman's other claims, there is some question as to whether those claims are still viable under Mississippi law. Some district courts have said that the MPLA "subsumes" other common-law claims of negligence against a product manufacturer or seller.

Lashley, 877 F. Supp. 2d at 471. Other district courts have stated that common-law negligence claims "can be brought alongside strict liability claims," but a determination as to the MPLA claims is dispositive of any coexisting common-law claims of product defect.

McSwain v. Sunrise Med., Inc., 689 F. Supp. 2d 835, 846 (S.D. Miss. 2010) (explaining how Mississippi law is equivocal on this point); see also Murray v. Gen. Motors, LLC, 2011 WL 3684517, at *3 (S.D. Miss. Aug. 22, 2011) ("[A] plaintiff's negligence claim cannot survive apart from his MPLA claim."). The Court prefers McSwain's articulation, because it has been sanctioned at least twice by the Mississippi Supreme Court. Nunnally v. R.J. Reynolds Tobacco Co., 869 So. 2d 373, 380-82 (Miss. 2004); Bennett v. Madakasira, 821 So. 2d 794, 808 (Miss. 2002), abrogated on other grounds by Hutzel v. City of Jackson, 33 So. 3d 1116 (Miss. 2010). Ultimately, all courts seem to agree that the distinction of whether common-law claims of negligence for product defects can or cannot exist outside the MPLA, i.e., whether they are subsumed by or exist alongside of, makes little practical difference because the similarities between the MPLA and common-law claims of negligence dictate that their outcome will be the same. See Jowers, 2009 WL 995613, at *4.

In fact, the Fifth Circuit has recognized the inherent overlap between strict liability claims and other common-law claims of

 $^{^5}$ It is unclear whether "subsumes" is considered to be roughly synonymous with the term "abrogates," <u>see Jowers v. BOC Group, Inc.</u>, 2009 WL 995613, at *3, (S.D. Miss. Apr. 14, 2009) <u>rev'd in part on other grounds by Jowers v. Lincoln Elec. Co.</u>, 617 F.3d 346 (5th Cir. 2010) (reversing the district court on the issue of damages only), or whether it expresses the sentiment of <u>McSwain</u> that negligence claims of product liability exist apart from but suffer the same fate as MPLA claims.

negligence in the context of harms caused by prescription-drug use. In <u>Swayze v. McNeil Laboratories</u>, <u>Inc.</u>, 807 F.2d 464 (5th Cir. 1987), the plaintiffs brought suit against a drug manufacturer, alleging that their seven-year-old son lost his arm, and ultimately his life, because the drug manufacturer failed to warn of the dangers of intravenously administering the anesthetic fentanyl. <u>Id.</u> at 467. After considering the plaintiffs' claims, the court determined that the plaintiffs' strict liability and negligence claims were subject to the same fate because the reasonableness of the defendant's conduct depended on the adequacy of the warning. <u>Id.</u> at 467. The Fifth Circuit agreed with this determination, stating that the principles undergirding the plaintiffs' negligence and strict liability claims against a drug manufacturer "merge into one inquiry: the adequacy of the defendant's warnings." <u>Id.</u>

The present circumstances, at least with regard to the Generic

⁶ The MPLA defines an adequate warning as:

^[0] ne that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.

Miss. Code Ann. § 11-1-63(c)(ii) (emphasis added).

Defendants, are similar, if not identical, to those in <u>Swayze</u>. <u>Lashley</u>, 877 F. Supp. 2d at 471. Chatman's injuries allegedly stem from her long-term use of metoclopramide, and her common-law theories of liability are premised on the inadequacy of the information provided to her through the Reglan-metoclopramide labeling. In Counts I and V, she alleges that the Defendants were negligent or grossly negligent in developing and monitoring their labeling. Am. Compl. ¶ 113. In Count III, she alleges that Defendants impliedly warranted through their labeling (the package inserts) that their drug was not unreasonably dangerous and was fit for its intended use. <u>Id</u>. ¶ 121. Even in Count IV, her fraud count, she alleges that the Defendants misrepresented, suppressed, or concealed critical information in connection with their labeling. Id. ¶ 126, 128, 129.

Despite her good-faith attempt to "plead around Mensing," the only conclusion that the Court can reach is that Chatman uses each claim to attack the adequacy of the labeling and each falls within Mensing's sphere. To be clear, even if the Generic Defendants knew that their labeling contained false information and knew that their labeling was causing serious harm to consumers, i.e., if they intentionally committed some form of fraud under Mississippi law in connection with their labeling, Mensing instructs that the Supremacy Clause prevents Mississippi from imposing liability on them for harms caused in connection with their labeling because federal law

renders them powerless to alter their drug's labeling under any circumstances. Mensing, 131 S. Ct. at 2577-78. Accordingly, Chatman's negligence, gross negligence, misrepresentation, suppression of the evidence, and fraud claims against the Generic Defendants must be dismissed with prejudice because those claims are pre-empted by the FDA's regulatory scheme.

B. Brand Defendants' Motion for Summary Judgment

1. Standard of review

As for the Brand Defendants, a different standard of review applies to their Motion for Summary Judgment. Summary judgment is apposite "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is 'material' if its resolution in favor of one party might affect the outcome of the lawsuit under governing law. An issue is 'genuine' if the evidence is sufficient for a reasonable jury to return a verdict for the non-moving party." Ginsberg 1985 Real Estate P'ship v. Cadle Co., 39 F.3d 528, 531 (5th Cir. 1994) (citations omitted). The party moving for summary judgment bears the initial responsibility of apprising the district court of the basis for its motion and the parts of the record which indicate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

"Once the moving party presents the district court with a properly supported summary judgment motion, the burden shifts to the

non-moving party to show that summary judgment is inappropriate."

Morris v. Covan World Wide Moving, Inc., 144 F.3d 377, 380 (5th Cir. 1998). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). But the nonmovant must "do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Moreover, "[t]he mere existence of a scintilla of evidence is insufficient to defeat a properly supported motion for summary judgment." Anderson, 477 U.S. at 252. Summary judgment must be rendered when the nonmovant "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp., 477 U.S. at 322.

2. Chatman's products liability claims

In her Amended Complaint, Chatman alleges the same claims against the Brand Defendants that she alleges against the Generic Defendants. Federal law does not preclude recovery from the Brand Defendants, and therefore they could be liable to Chatman under Mississippi law for Chatman's products liability claims, see Wyeth v. Levine, 555 U.S. 555 (2009), provided Chatman could prove that she took Reglan. Unfortunately for Chatman, she has admitted that

⁷ To be clear, the Court's analysis regarding Chatman's claims against the Brand Defendants is a matter of Mississippi law and has nothing to do with Mensing, or federal law generally. This is true

she did not take Reglan. There is no question, then, that Chatman's products liability claims against the Brand Defendants are foreclosed by Mississippi law because Chatman did not take their drug. E.g., Moore ex rel. Moore v. Mississippi Valley Gas Co., 863 So. 2d 43, 46 (Miss. 2003) ("[I]t is incumbent upon the plaintiff in any products liability action to show that the defendant's product was the cause of the plaintiff's injuries."). Even Chatman appears to concede this point in her brief. See Pl.'s Resp. Br. at 2 ("Plaintiff's claims with regard to Brand Defendants do not relate to the composition or manufacture of the metoclopramide Ms. Chatman ingested."). Further, inasmuch as any of Chatman's common-law claims are asserted against the Brand Defendants because they manufactured, produced, or sold Reglan, those claims are also in essence products liability claims and must suffer a similar fate.

3. Chatman's misrepresentation claims

Chatman, like many other plaintiffs who have found themselves in a similar predicament after <u>Mensing</u>, attempts to impose some liability on the Brand Defendants by virtue of the their connection to the Reglan-metoclopramide labeling. See Pl.'s Resp. Br. at 2. The

both as to whether federal law prohibits the imposition of liability upon the Brand Defendants or creates liability for the Brand Defendants. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352-53 (2001). Neither party makes either of these arguments in their briefs, although Chatman makes many Buckman-type factual assertions in her Amended Complaint. The Brand Defendants may not be liable to Chatman for failure to comply with the FDA's rules or regulations. Id.

theory Chatman advances has come to be known as "innovator" liability. See Allen Rostron, Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers, 60 Duke L.J. 1123, 1176 (2011). The basic idea behind the theory is that the brand-name drug companies are responsible for creating and monitoring the content of both the brand-name and generic drug's labeling and therefore they can be liable for the harms caused by the labeling under common-law theories of liability, typically misrepresentation theories. The hope is that by attributing the harm to the labeling, a plaintiff may hold the brand-name manufacturer liable, particularly since the Supreme Court recently held that federal law protects generic manufacturers from any liability. This theory is not new, and as the Brand Defendants point out in a page-long footnote of string citations in their brief, see B. Defs.' Br. at 17-18 n.10, it has been rejected by the overwhelming majority of district courts, including three courts applying Mississippi law. See, Gardley-Starks, 2013 WL 139900, at *5; Lashley, 877 F. Supp. 2d at 473; In re Darvocet, 856 F. Supp. 2d 904, 909-910 (E.D. Ky. Mar. 5, 2012).

While the theory's near universal rejection by other district courts raises questions as to its viability, <u>Erie</u> requires this Court to carefully apply Mississippi law. <u>E.g.</u>, <u>Capital City Ins.</u>

<u>Co. v. Hurst</u>, 632 F.3d 898, 902 (5th Cir. 2011). And Mississippi law—regardless of whether other jurisdictions would agree with its

rationale—does provide some support for Chatman's argument. Recently, the Mississippi Supreme Court in <u>Lawson v. Honeywell</u> <u>International, Inc.</u>, 75 So. 3d 1024 (Miss. 2011), appeared to sanction "designer" liability—for lack of a better term—and because of its resemblance to the "innovator" theory of liability advanced by Chatman, that case deserves fuller discussion.⁸

a. Lawson v. Honeywell International, Inc.

In <u>Honeywell</u>, Pamela Lynn Lawson was involved in an automobile accident and alleged that her injuries were caused by her seatbelt buckle malfunctioning. <u>Honeywell Intern.</u>, Inc., 75 So. 3d at 1026. She brought suit against the seatbelt buckle designer, Honeywell International, Inc., in state court under theories of strict liability (MPLA claim), negligence, and negligence per se. <u>9 Id.</u> Following discovery, the trial court granted summary judgment for Honeywell as to all claims. It concluded that Honeywell, which was neither a manufacturer nor a seller of the seatbelt buckle, could not be liable under the MPLA for Honeywell's products liability claims. The court also determined that the MPLA was her exclusive

⁸ The Court uses the terms "innovator liability" and "designer liability" purely for reference. As is apparent from the Court's discussion below, both of these terms should not be used to short-cut the careful application of longstanding tort rules.

⁹ It is unclear from the opinion whether Lawson knew that Honeywell had not manufactured the seatbelt buckle, but it appears that she did not. She also sued Key Safety Systems, the actual manufacturer of the buckle, but she settled her claim against the manufacturer out of court. Id. at 1026.

remedy, even though she also had pleaded common-law claims against Honeywell. <u>Id.</u> at 1025. Lawson appealed the judgment, and on appeal the Mississippi Supreme Court considered (1) whether the trial court erred in holding that Honeywell could not be liable under the MPLA and (2) whether the trial court erred in holding that the MPLA was Lawson's exclusive remedy against Honeywell. Id. at 1027.

As to the first question, the Mississippi Supreme Court agreed with the trial court that Honeywell did not fall within the scope of the MPLA because Honeywell did not "produce" the seatbelt buckle. Id. at 1028-29. It reasoned that the MPLA only applies to manufacturers or sellers, and after consulting Black's Law Dictionary, concluded that because Honeywell did not "produce" the seatbelt buckle it was not a manufacturer. In its view, Honeywell was a "mere designer", id. at 1030, and mere designers are not subject to the MPLA. Id. at 1029. As to the second issue, however, the supreme court disagreed with the trial court that the MPLA was Lawson's exclusive remedy against Honeywell. It explained that the MPLA is only applicable to manufacturers and sellers, and because Honeywell was a "nonmanufacturing designer," the trial court erred by ruling that the MPLA precluded other common-law claims. Id. at 1030. Accordingly, the Mississippi Supreme Court remanded the case to the trial court so that Lawson's case could proceed to trial against Honeywell on her remaining claims. Id. at 1025.

b. Whether <u>Lawson v. Honeywell International</u>, <u>Inc.</u> indicates that the Brand Defendants can be liable for Chatman's

misrepresentation claims

Chatman agues that the Brand Defendants are in a similar position to a nonmanufacturing designer and thus may be liable for the dissemination of false and misleading information that they knew she would rely upon and that proximately caused her injuries. Pl.'s Resp. Br. at 11. The Brand Defendants' response to this assertion is two-fold. First, they claim to be manufacturers in the present suit, not designers. See B. Defs.' Br. at 11-13. In making this assertion, the Brand Defendants read Honeywell to hold that "negligence claims against a 'designer' of a product that is not also a 'manufacturer or seller' of the product can proceed as independent claims outside the MPLA." B. Defs.' Reply Br. at 3. But that is not what the Mississippi Supreme Court said. Rather, it stated that "a person or entity other than the manufacturer or seller . . . may be held liable " <u>Id.</u> at 1029-30 (emphasis added). It is clear from the entire context of the opinion that the classification of the defendant depends upon the product in question, which in Honeywell's case was the seatbelt buckle.

The Brand Defendants are manufacturers of Reglan. Chatman clearly states in her brief that she is suing the Brand Defendants not because they made Reglan or designed metoclopramide, but because they are responsible for the warning that she was given. Pl.'s Resp. Br. at 2, 15. This allegation is substantiated by the scattered factual allegations and legal theories throughout her Amended

Complaint. In order to prevail on Chatman's product liability claims, the Brand Defendants have made exceedingly clear that they were not the manufacturer of the drug Chatman ingested. They have been granted summary judgment on Chatman's products liability claims for this reason alone. Now they seek summary judgment on the ground that they are manufacturers. In addition to the case law, commonsense and fairness dictates that they cannot have it both ways. For the purposes of Chatman's misrepresentation claims, the Brand Defendants are not manufacturers.

Second, the Brand Defendants argue that <u>Honeywell</u> does not impose upon them a "new" duty under Mississippi law to protect a consumer from harms caused by a product manufactured by another. <u>See</u> B. Defs.' Reply Br. at 5. This assertion may be true, but Chatman's common-law claims are not necessarily foreclosed for this reason. <u>Honeywell</u>, at minimum, establishes that (1) the MPLA only applies to manufacturers and sellers and (2) common-law claims against a nonmanufacturer or non-seller, even when they arise from the same set of facts that support a products liability claim against another defendant, are not subject to or "subsumed by" the MPLA. <u>See Honeywell Intern.</u>, Inc., 75 So. 3d at 1030 (distinguishing <u>Jowers</u> by stating that manufacturers and nonmanufacturers must be treated differently); <u>see also</u>, <u>Hankins</u>, 2011 WL 6180410, at *6 n.4. Based on these two premises, what <u>Honeywell</u> means to Chatman is simply that she may maintain her misrepresentation claims against the Brand

Defendants even though they did not manufacture the product that contributed to her injury. Dee supra n.9; see also Jowers, 2009 WL 995613, at *9 (deciding before Honeywell that "a claim for negligent misrepresentation . . . may not be a 'product liability claim.'");

R.J. Reynolds Tobacco Co. v. King, 921 So. 2d 268, 271-72 (Miss. 2005) (suggesting before Honeywell that the plaintiff's negligent misrepresentation claim may proceed independent of her products liability claim).

Accordingly, Chatman's claims cannot be dismissed simply as products liability claims, as the Brand Defendants urge. 11 See B.

The Court recognizes that the gravamen of Chatman's complaint against the Brand Defendants can be viewed as a failure-to-warn claim against a nonmanufacturer. But it does not follow from this recognition that Chatman has no common-law claim. The same allegation could be made about Lawson's "design-defect" claim against Honeywell. As is apparent from the discussion of whether a properly-pleaded products liability claim subsumes other common-law claims, theories of liability, particularly in this area of the law, tend to overlap. See Jowers, 2009 WL 995613, at *4. The question is not what theory most appropriately applies to the circumstances of this case, but simply whether the Brand Defendants may be liable under the common law.

Defendants might appear inconsistent with the finding against the Generic Defendants. But, to reiterate, the Court did not find that Chatman's common-law claims against the Generic Defendants are viewed as "subsumed by" the MPLA; nor did the Court say that Chatman's claims against the Generic Defendants had to be thought of as products liability claims. Instead, it determined that they were subject to the same fate because both Chatman's common-law and statutory claims attacked the adequacy of the Reglan-metoclopramide labeling. The difference is, of course, that federal law dooms all claims connected to the Generic Defendants' labeling, whether they be failure-to-warn claims or fraud claims, whereas federal law, at least as far as this Court is aware, does not prevent Chatman's claims against the Brand Defendants. The argument before the Court

Defs.' Br. at 1, 5-10, 13-14 ("This is a product liability case"). In reaching this conclusion, the Court recognizes that it does not believe Mississippi is in step with the majority view. See, e.g., Demahy, 702 F.3d at 183 n.4. Speaking in broad terms, most district courts have dismissed claims identical to Chatman's after concluding that such claims can only be products liability claims under the applicable state's laws. Id. That viewpoint is often bolstered by Foster's no-duty reasoning, discussed below. With that said, the Court does not view Honeywell as imposing some "new" or "innovative" theory of state-law liability, see Gardley-Starks, 2013 WL 139900, at *4 (finding that whatever duty was imposed in Honeywell applies strictly to nonmanufacturing designers), Washington ex rel. Washington v. Medicis Pharms. Corp., 2013 WL 496063, at *4 (S.D. Miss. Feb. 7, 2013) (stating that Honeywell did not create a new duty under Mississippi law); rather, Honeywell simply stands for the proposition that Chatman may pursue her common-law claims under "old" state law theories of liability, even though she may have been injured by a product manufactured by another.

c. Whether the Brand Defendants owe Chatman a duty under Mississippi Law

Appearing to recognize that <u>Honeywell</u> might support this conclusion, the Brand Defendants go on to assert that finding that they owed a duty to Chatman in these circumstances would abandon

depends entirely upon Mississippi law.

settled principles of Mississippi law and "saddle" Mississippi with an aberrant tort rule. While the absence of an analogous case imposing liability appears to underpin their assertion, more fundamentally, they imply that because they had no relationship with Chatman, they had no duty to her. See B. Defs.' Br. at 15. Even if this fact was undisputed, 12 the legal premise advanced by the Brand Defendants is overbroad. As a general rule, in the context of negligence claims a relationship is not necessary for a duty to exist. Scafide v. Bazzone, 962 So. 2d 585, 592 (Miss. Ct. App. 2006). 13 In fact, the Mississippi Legislature has abolished the requirement of privity "in all causes of action for personal injury . . . brought on account of negligence." See Miss. Code Ann. § 11-7-

The Court is mindful that one of Chatman's allegations is that she was given the Reglan warning. It appears from the relevant statute that the brand-name drug is typically prescribed, with the prescribing doctor indicating whether the generic equivalent may be substituted. Miss. Code Ann. § 73-21-117. The Parties have not briefed this issue, but it is conceivable that some "relationship"—via the learned intermediary—might exist.

opinion which states that "the absence of the relationship does prevent the creation of a duty." <u>Scafide v. Bazzone</u>, 962 So. 2d 585, 592 (Miss. Ct. App. 2006). But in <u>Scafide</u>, this statement is intended to apply only to medical malpractice claims, as the context makes exceedingly clear. <u>Id.</u> The sentences preceding the <u>Scafide</u> Court's statement state that the existence of a duty <u>does not</u>, at least in a typical negligence analysis, depend upon the existence of a relationship. <u>Id.</u> ("Determining whether a duty is owed is approached by asking 'whether the plaintiff's interests are entitled to legal protection against the defendant's conduct,' rather than focusing solely on the level of relationship between parties." (quoting <u>Prosser and Keeton on Torts</u> § 53, 356-58 (5th ed. 1984)) (emphasis added)).

20. Even in the context of negligent misrepresentation claims, it is settled Mississippi law that a defendant may be liable to a third-party plaintiff, in spite of the fact that the defendant had no "relationship" with the third-party plaintiff. See generally, Clark v. St. Dominic-Jackson Mem'l Hosp., 660 So. 2d 970 (1995) (adopting Restatement (Second) of Torts § 311 (1965)). Having carefully considered Mississippi law on point, the Court finds that whether the Brand Defendants must have a relationship with Chatman in order to have some duty to her depends upon the type of alleged misrepresentation. Jowers, 2009 WL 995613, at *6 (explaining that the case law distinguishes between representations of misfeasance and nonfeasance, although implying that there is not necessarily a bright-line difference between the two); Ruth v. A.O. Smith Corp., 2005 WL 2978694, at *4-*5 (N.D. Ohio Oct. 11 2005) (interpreting Mississippi law).

To elaborate briefly, the Brand Defendants could have a duty to Chatman without having a relationship with her if she is alleging that the warning given to her contained false information. Clark, 660 So. 2d at 974. In an affirmative misrepresentation case, even though a defendant does not have a relationship with the plaintiff, it is still possible for the defendant to be liable for causing the plaintiff's physical injury if the plaintiff reasonably relies on

false information provided by the defendant. 14 Id. But whether the Brand Defendants can be liable for a misrepresentation claim based on an omission-which appears to be the crux of the Brand Defendants' no-duty argument and, to be fair, appears to be Chatman's primary theory of her case-requires a different duty analysis. The question under the omission theory is whether the Brand Defendants had a duty to disclose to Chatman certain information that they knew or should have known would have prevented her injuries. E.g., Taylor v. S. Farm Bureau Cas. Co., 954 So. 2d 1045, 1049 (Miss. Ct. App. 2007) (citing cases). And the answer to this question, under Mississippi law, depends upon whether the parties had a fiduciary or special relationship. Taylor, 954 So. 2d at 1049; Jowers, 2009 WL 995613, at *6 (stating that a special relationship is necessary in order for a plaintiff to maintain a fraud claim). But the Brand Defendants do not tailor their arguments to the type of misrepresentation alleged, opting instead for a universal no-duty argument based upon a few unrelated Mississippi cases and a Fourth Circuit opinion.

¹⁴ See also Restatement (Second) of Torts § 310, which states:

An actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by the other or a third person in reliance upon the truth of the representation, if the actor (a) intends his statement to induce or should realize that it is likely to induce action by the other, or a third person, which involves an unreasonable risk or physical harm to the other, and (b) knows (i) that the statement is false, or (ii) that he has not the knowledge which he professes.

d. Foster v. American Home Products Corporation, et al.

To this point, it is appropriate for the Court to address the "mountain of authority" cited by the Defendants because it is upon this authority that the Brand Defendants primarily rely for their no-duty argument. The case that has unquestionably proven most fatal to Chatman's miscast "innovator" theory of liability is Foster v. American Home Products Corporation, 29 F.3d 165 (4th Cir. 1994). See B. Defs.' at 19-20 (pitting the "mountain of authority" that is Foster and its progeny against the "outliers" Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Ct. App. 2008), Kellogg v. Wyeth, Inc., 762 F. Supp. 2d 694 (D. Vt. 2010), and now, presumably, Wyeth, Inc. v. Weeks, --- So.3d ----, 2013 WL 135753 (Ala. Jan. 11, 2013) (draft opinion)). In a situation similar to the case at bar, a Fourth Circuit panel determined that a brand-name manufacturer owed "no duty of care" to the plaintiffs' daughter who died after ingesting the generic drug. Foster, 29 F.3d at 167. In reaching the

The Fifth Circuit has stated that "decisions that relied upon Foster to create a similar rule in Louisiana remain valid."

Demahy, 702 F.3d at 184. The Court views this holding as specific not only to cases decided under Louisiana law but also sees it as limited to a particular argument advanced by Demahy in support of her Rule 60(b) Motion. The Fifth Circuit did not directly address Foster or its rationale. Instead, the Fifth Circuit's statement was directed at repudiating Demahy's assertion that Foster was implicitly reversed by Mensing, and thus the decision relying on Foster was also reversed. This Court's analysis has nothing to do with the dicta addressed by the Fifth Circuit, and its impact on the validly of that case. It is Foster's rationale, as it is presented by the Brand Defendants and as it applies to Mississippi law, with which the Court is concerned.

conclusion, the Fourth Circuit, applying Maryland law, quipped "[w]e think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." <u>Id.</u> at 169-70.

As an initial matter, it does not appear that Maryland's version of a negligent misrepresentation cause of action for physical harm-at least as it was expressed by the Foster Court-is consistent with Mississippi's. Compare id. at 171 (providing the first element of a negligent misrepresentation claim as "the defendant, owing a duty of care to the plaintiff, negligently asserts a false statement") (emphasis in original) (citation omitted), with Clark, 660 So. 2d at 974 ("One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results.") (emphasis added). But as to the issue of duty itself, despite expressing its finding in terms of foreseeability, the Fourth Circuit never explained why the brand manufacturer could not have reasonably foreseen the type of harm the decedent suffered as a result of an allegedly inadequate warning. In fact, the court never discussed forseeability at all. The only fact cited by the Fourth Circuit in support of its no-duty determination was that "Brandy Foster was injured by a product that Wyeth did not manufacture." Id. While this fact may be pertinent to a forseeability analysis, it is only dispostive if the Fourth Circuit continued to view the Fosters' misrepresentation claim as

a products liability claim. <u>See Foster</u>, 29 F.3d at 168 ("The Fosters are attempting to hold Wyeth liable for injuries caused by another manufacturer's product, and we are persuaded that the Maryland courts would reject this effort to circumvent the necessity that a defendant be shown to have manufactured the product that caused an injury prior to being held liable for such injury."). In sum, whether the Fosters' misrepresentation claim was a products liability claim appears to have been the beginning and end of the Fourth Circuit's "duty" analysis.

Moreover, if foreseeability had been the <u>Foster</u> Court's "principal determinant," <u>Foster</u>, 29 F.3d at 171, finding that no duty existed on forseeability grounds presumes that the brand manufacturers had some general duty to use reasonable care not to create a risk of physical harm to individuals who were foreseeable.

<u>See W. Jonathan Cardi, Purging Foreseeability</u>, 58 Vand. L. Rev. 739, 767 & ns.141 & 142 (2005). Under Mississippi law, this finding would be proper only to the extent that no reasonable juror would find that the type of injury the plaintiff suffered was not foreseeable. See Robert A. Weems & Robert M. Weems, Mississippi

¹⁶ As more than one commentator has explained, whether foreseeability is an issue of fact or an issue of law often becomes a matter of expediency. Finding that the Brand Defendants owed no duty to Chatman under Mississippi law because her injury was not foreseeable would be—at least in this Court's view—a jury decision masquerading as a legal decision. See Cardi, supra, at 741 ("By folding considerations of breach and proximate cause into the ambit of duty, judges also skirt responsibility to decide such matters, if at all, according to the deferential "no reasonable jury"

Law of Torts § 3:21 (2d ed.) (stating that foreseeability is an issue for the factfinder) (citing cases). Given the longstanding applicability of the FDA regulations to a brand-name manufacturer's activities and the sheer frequency with which this particular injury or type of injury occurs, see B. Defs.' Br. at 17-18, there is at least a genuine issue of material fact as to whether Chatman's injury was the type that could reasonably be expected to flow from a misrepresentation in the Reglan-metoclopramide labeling. See Glover ex rel. Glover v. Jackson State Univ., 968 So. 2d 1267, 1269 (Miss. 2007); see also Rostron, supra, at 1174 ("The brand-name manufacturers' characterizations of the situation, however, are hard to square with reality.").

Turning back to the present case, as explained above, under Mississippi law the existence of a duty depends upon the nature of the parties' relationship only if Chatman is alleging that she was harmed not because of what the Brand Defendants did communicate to her, i.e., misfeasance, but because of what the Brand Defendants failed to communicate to her, i.e., nonfeasance. <u>See Jowers</u>, 2009 WL 995613, at *6. Absent a special or fiduciary relationship with

standard—the standard pursuant to which a court must decide as a matter of law what is typically a jury question."); Dan B. Dobbs, Paul T. Hayden & Ellen M. Bublick, The Law of Torts § 256-57 (2d ed. 2011) (listing six "objections to determining duty by deciding foreseeability of harm"); see also, e.g., A.W. v. Lancaster Cnty. Sch. Dist. 0001, 784 N.W.2d 907, 914 (Neb. 2010) ("So, by incorporating foreseeability into the analysis of duty, a court transforms a factual question into a legal issue and expands the authority of judges at the expense of juries or triers of fact.").

Chatman, the Brand Defendants would not have a duty to prevent Chatman's injury-even if her injury was foreseeable-as long as the warning given to Chatman was not false and that it contributed to her injury. The See, Clark, 660 So. 2d at 974. In that sense, the situation is analogous to the duty-to-aid cases, which provide that "the fact that an actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action." Higginbotham v. Hill Bros. Const. Co., Inc., 962 So. 2d 46, 56 (Miss. Ct. App. 2006) (quoting Restatement (Second) of Torts § 314 (1965)); see also John M. Adler, Relying Upon the Reasonableness of Strangers: Some Observations About the Current State of Common Law Affirmative Duties to Aid and Protect Others, 1991 Wis. L. Rev. 867, 872 ("The common law's reluctance to require one to render aid to a stranger rests upon the distinction between misfeasance and nonfeasance."). To put it as simply as possible, Chatman must show that false labeling caused her injury. It is not enough to show that the Brand Defendants could have (or should have) strengthened the labeling to

¹⁷ To be clear, even if a duty existed, the Brand Defendants still may not be liable. Finding that the Brand Defendants had a "duty" in the present case would not mean that the scope of that duty extended to the harm suffered by Chatman. Among other things, Chatman would have to show that her reliance on any false misrepresentation was reasonable, Clark, 660 So. 2d at 974, and reasonable reliance turns on whether the type of injury that she suffered was foreseeable. Hosford v. McKissack, 589 So. 2d 108, 112 (Miss. 1991). As stated above, that is a fact issue. Id. There is, of course, also the issue of proximate cause of the injury, which neither party has addressed.

prevent her injury.

e. Conclusion

Both Parties did an excellent job briefing what appears to be a difficult area of Mississippi law, but neither Party cited cases or raised facts that this Court deems dispositive to Chatman's misrepresentation claims. The Court suspects that Chatman is alleging that the problem with the warnings that were given to her were that they were not sufficient to protect her from injury. This allegation would be a misrepresentation claim by omission. Moreover, judging simply from the face of the pleadings, it appears doubtful to this Court that the relationship between Chatman and the Brand Defendants can be considered a special or fiduciary one. See supra n.12. Chatman, however, should be afforded the opportunity to address these legal issues and explain her position. The Brand Defendants moved for summary judgment on the basis of one particular fact—that they did not manufacture the pills that Chatman consumed. This fact entitles them to summary judgment in part. While the Court

¹⁸ Perhaps this observation is assumed, but a failure-to-warn products liability claim is more closely related to a misrepresentation claim based on an omission because a failure-to-warn claim, much like an implied warranty claim, imposes a positive duty on the product manufacturer to ensure the safety of its product. It is for this reason, perhaps, that courts have stated that brand name manufacturers have no duty to consumers of generic drugs under state law theories. This Court simply qualifies that assessment to state that brand name manufacturers-provided they do not have some special relationship to consumers of generic drugs which this Court has overlooked-owe no duty to consumers of generic drugs as long as the warnings given to the generic drug consumers are not false and therefore contribute to the plaintiff's injury.

fully anticipates the Brand Defendants filing a second dispositive motion, their present motion is denied as to Chatman's misrepresentation claims.

V. ORDERS

In light of the foregoing, IT IS HEREBY ORDERED THAT the Generic Defendants' Motion for Judgment on the Pleadings [docket no. 70] is GRANTED. All claims against Defendants Pliva, Inc., Barr Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., are DISMISSED WITH PREJUDICE. IT IS ALSO HEREBY ORDERED THAT the Defendants' Motion for Summary Judgment [docket no. 72] is GRANTED IN PART AND DENIED IN PART. Inasmuch as Chatman has alleged claims against the Brand Defendants under the MPLA or other common-law products liability theories, those claims are DISMISSED WITH PREJUDICE. Consistent with the views expressed above, Chatman's state-law misrepresentation claims survive the Brand Defendants' Motion.

SO ORDERED, this the 27th day of March 2013.

/s/ David Bramlette
UNITED STATES DISTRICT COURT