IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

JOHN ANTHONY RUSK and JUDY RUSK, individually and as Administrator of the Estate of JOHN ANTHONY RUSK, Plaintiffs,	§	
V.	§	A-14-CV-00549-LY-ML
WYETH-AYERHERST LABORATORIES, INC.; SANDOZ INC.; TEVA PHARMACEUTICALS USA INC.; BARR LABORATORIES, INC.; AND EON LABS; Defendants.	§	

REPORT AND RECOMMENDATION
OF THE UNITED STATES MAGISTRATE JUDGE

TO THE HONORABLE LEE YEAKEL
UNITED STATES DISTRICT JUDGE

Before the Court are the Motion to Dismiss [Dkt. # 21] filed by Defendant Sandoz, Inc. ("Sandoz"), the Response in opposition thereto filed by Plaintiffs [Dkt. #27], and Sandoz' Reply in support thereof [Dkt. #29].[1]

The Motions were referred by United States District Judge Lee Yeakel to the undersigned for a Report and Recommendation as to the merits pursuant to 28 U.S.C. § 636(b), Rule 72 of the Federal Rules of Civil Procedure, and Rule 1(d) of Appendix C of the Local Rules of the United States District Court for the Western District of Texas. After reviewing the pleadings, the relevant case law, as well as the entire case file, the undersigned issues the following Report and Recommendation to the District Court.

[1] This Motion to Dismiss addresses claims against Sandoz only and does not implicate the Complaint against the other four defendants named as parties in this case.

I. BACKGROUND

This is a product liability action against the makers and promoters of Cordarone® and its generic version, amniodarone. Cordarone is a pharmaceutical that was approved by the FDA in 1985 as "a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies." Compl. at ¶¶ 41-42. Amniodarone is the FDA-approved generic bioequivalent of Cordarone. *Id.* at ¶ 45.

A. John Anthony Rusk's Use of Amniodarone

Plaintiffs allege John Anthony Rusk died from taking amniodarone, a generic version of Cordarone. Compl. ¶ 47. According to the Complaint, Mr. Rusk was prescribed a 90-day course of amniodarone as a treatment for atrial fibrillation, an "off-label" use of the drug. *Id.* at ¶ 47-48. Mr. Rusk filled his prescription on August 24, 2011 and took the drug as prescribed. *Id.* at ¶48. Mr. Rusk did not receive a Medication Guide, which outlines the risks and benefits of the drug, with his prescription. *Id.* at ¶ 50. He was not informed of the potentially fatal side effects associated with the drug. *Id.* Mr. Rusk was not aware that his use of the drug was an "off-label" use. *Id.* at ¶ 52.

Amniodarone's manufacturers are responsible for ensuring that Medication Guides are available for distribution to patients. 21 C.F.R. § 208.24. It is the end distributor (such as a pharmacy), however, that is responsible for actually providing the Medication Guide to the patient. *See id.* Mr. Rusk's prescription was filled by a CVS pharmacy. Compl. at ¶ 48, n. 14. Plaintiffs allege that "According to the Pharmacies, no manufacturer is providing them or the patient's [sic] medication guides." Compl. at ¶ 137. The amniodarone tablets contained in Mr. Rusk's prescription were marked with an NDC number identifying Defendant Sandoz as their

marketer, manufacturer, and distributor. *Id.* at ¶ 49. Plaintiffs assert Sandoz failed to ensure that the Medication Guide was provided to Rusk. *Id.* at ¶ 50.

In the spring of 2012, Mr. Rusk began experiencing many of the side effects outlined in the amniodarone Medication Guide, including shortness of breath, wheezing, impaired vision, and leg, stomach, and chest cramps. *Id.* at ¶¶ 56, 58. Mr. Rusk died on May 1, 2012 at the age of 84. *Id.* at ¶ 59. Plaintiffs allege amniodarone-induced lung disease was a cause of death. *Id.*

Plaintiffs have sued various pharmaceutical companies, including Sandoz, the maker of the amniodarone prescribed to Mr. Rusk. Plaintiffs allege the Defendants, specifically including Sandoz, were aware of increasing reports of adverse events related to off-label use of amniodarone between 1985, when Cordarone was initially approved in an abbreviated procedure, through the time it was prescribed to Mr. Rusk in 2011, through direct reports from health care providers and consumers, multiple official FDA label revision requirements, and through the FDA's Adverse Event Reporting System (AERS). *Id.* at ¶¶ 61-83; 86-90. Plaintiffs allege the Defendants, specifically including Sandoz, nevertheless aggressively marketed amniodarone as a safe, first-line drug for various off-label cardiac therapies, such as that prescribed for Mr. Rusk. *Id.* at ¶¶ 92-96, 103-106. Plaintiffs allege the generic manufacturers, including Sandoz, actively promoted and "pushed" off-label use of amniodarone both through direct marketing and through "piggybacking" on the off-label marketing efforts of Defendant Wyeth, the manufacturer of the brand-name version of the drug. *Id.* at ¶¶ 92-105.

Based on these factual allegations, Plaintiffs assert claims under Texas state law that the wrongful death of John Anthony Rusk was "directly and proximately caused by the negligent actions of the Defendants as related to the manufacture, marketing, distribution, and sale of Cordarone®/Amniodarone as described herein." *Id.* at ¶ 131. Plaintiffs further allege the

Defendants "are guilty of gross negligence for failure to provide the FDA required medication guide," *id.* at ¶ 138, and the failure to provide Mr. Rusk the medication guide was a direct and proximate cause of Plaintiff's damages. *Id.* at ¶ 139. Defendant Sandoz has responded with a motion to dismiss, alleging that all of Plaintiffs' claims are preempted by FDA regulations and that, in the alternative, Plaintiff's generalized factual allegations are insufficient to satisfy Federal Rule of Civil Procedure 12(b)(6) and, to the extent Plaintiffs' claims sound in fraud, Federal Rule of Civil Procedure 9(b). *See generally* Mot. Dism. [Dkt. #21].

B. The Unique Regulatory Framework Applicable to Generic Drugs

Plaintiffs' allegations must be read against the backdrop of the comprehensive regulatory scheme affecting the manufacture and sale of pharmaceuticals in the United States. Pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), the FDA regulates the approval of both brand name and generic drugs. See 21 C.F.R. § 314.50(c)(2)(i) (brand name); 21 C.F.R. §314.94(a)(8) (generic). The amniodarone manufactured by Sandoz is a generic; therefore the court will focus here on the regulatory scheme applicable to generic drugs.

Generic drugs are "designed to be a copy of a reference listed drug (typically a brand name drug), and thus identical in active ingredients, safety and efficacy." *PLIVA, Inc. v. Mensing*,____ U.S. ____, 131 S.Ct. 2567, 2574 (2011). Recognizing this "duty of sameness," the approval requirements for generic drugs are streamlined to require only submission of an Abbreviated New Drug Application (ANDA) showing a generic drug is identical in all material respects to a previously-approved reference drug. 21 U.S.C. § 355(j)(2)(A). These streamlined regulations require that the "labeling proposed [for an ANDA] is the same as the labeling approved for the [brand name drug]." *Mensing*, 131 S.Ct. at 2574 (citing 21 U.S.C. § 355(j)(2)(A)(v); 21 U.S.C. § 355(j)(4)(G)). Therefore, an ANDA applicant need only

demonstrate that its "warning label is the same as the brand name's" to receive FDA approval. *Mensing*, 131 S.Ct at 2574. Upon receiving FDA approval of an ANDA, the only duty incumbent upon a generic manufacturer under federal law with respect to its warnings is an ongoing "duty of sameness" — to ensure its generic drug's labeling remains identical to the Reference Listed Drug ("RLD") to which it is required to remain equivalent. *Id*. at 2574-75. Generic manufacturers are prohibited from independently changing their labeling in any respect without prior FDA approval. *Id*. at 2577 ("Federal drug regulations, as interpreted by the FDA, prevented the manufacturers from independently changing their generic drugs' safety labels."); *see also* 21 C.F.R. § 314.150(b)(10) (authorizing FDA to revoke approval of a generic drug if its labeling "is no longer consistent with that for the listed drug").

This continuing federal "duty of sameness" extends beyond the labeling to the design of the drug as well. *See generally Mutual Pharm. Co., Inc. v. Bartlett*, ___ U.S. ____, 133 S.Ct. 2466 (2013). To gain and keep ANDA approval, generic manufacturers must show their products are bioequivalent to the brand name or reference listed drug. *See* 21 U.S.C. §355(j)(2)(A)(i)-(iii) (ANDA applicants must demonstrate that a generic drug contains the same active ingredients; employs the same route of administration; presents the same dosage form; and exhibits the same strength as its brand name counterpart). As the *Mensing* court explained, federal law explicitly requires a generic drug to be "identical [to its branded equivalent] in active ingredients, safety, and efficacy," just as each generic drug must "ensur[e] that its warning label is the same as the brand name's." *Mensing*, 131 S.Ct at 2574 n.1. Because of this broadly applicable "duty of sameness," the Supreme Court has held in both *Mensing* and *Bartlett* that product liability claims against generic drug manufacturers based on theories of "failure to warn"

or "design defect" are preempted by federal law. *Mensing*, 131 S.Ct. at 2577-78; *Bartlett*, 133 S.Ct. at 2480.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(6) allows the court to dismiss a claim that, on its face, "fails to state a claim upon which relief may be granted." In reviewing a motion to dismiss for failure to state a claim, the court must accept as true all well-pleaded facts in the complaint, and must view the allegations as a whole in the light most favorable to the non-movant. *Scanlan v. Texas A&M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003); *Collins v Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000).

Although Federal Rule of Civil Procedure 8 mandates only that a pleading contain a "short and plain statement of the claim showing that the pleader is entitled to relief," this standard demands more than unadorned accusations, "labels and conclusions," "a formulaic recitation of the elements of a cause of action," or "naked assertion[s]" devoid of "further factual enhancement." *Bell Atl. v. Twombly*, 550 U.S. 544, 555-57, 127 S. Ct. 1955, 1965-66 (2007). Thus, in considering a motion to dismiss, the court must initially identify pleadings that are no more than legal conclusions not entitled to the assumption of truth, then assume the veracity of well-pleaded factual allegations and determine whether those allegations plausibly give rise to an entitlement to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 679, 129 S. Ct. 1937, 1950 (2009). If not, "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)).

To the extent a complaint alleges claims sounding in fraud, Federal Rule of Civil Procedure 9(b) requires that plaintiffs go a step further: the underlying factual circumstances must be plead "with particularity." *Id.* "Put simply, Rule 9(b) requires 'the who, what, when,

where, and how' to be laid out." *Benchmark Elecs. v. J.M. Huber Corp.*, 343 F.3d 719, 724 (5th Cir. Tex. 2003) (citing *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 179 (5th Cir. 1997)).

III. ANALYSIS

A. Preemption of Claims Based on Failure to Warn or Design Defect

Defendants assert Plaintiffs' claims fail as a matter of law because they are preempted by *Mensing*, 131 S.Ct. at 2577-78, and *Bartlett*, 133 S.Ct. at 2480. As noted above, *Mensing* holds that federal law preempts state law tort claims premised on alleged failure to warn of risks of generic drugs, because such claims conflict with federal law requiring generic manufacturers to conform their warnings to the equivalent brand name product. 131 S.Ct. at 2577-78. The Supreme Court reinforced and expanded *Mensing*'s scope to include design defect claims and claims alleging a duty to withdraw from the market in *Bartlett*, 133 S.Ct. at 2480.

The Fifth Circuit has adopted a broad reading of both *Mensing* and *Bartlett*, upholding dismissals of a wide variety of claims whose factual allegations boil down to complaints of "failure to warn" or "design defect" as preempted by federal law. *See, e.g.*, *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474 and n.3 (5th Cir. 2014) (rejecting "parallel" state tort claims as preempted and noting in dicta that "failure to warn is the 'only valid claim' in a suit for personal injuries caused by prescription drugs in Texas); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (*Mensing* forecloses all claims alleging "failure to communicate" approved warnings, and further preempts claims based on failure to test and inspect the product because "any 'useful' reporting [of the test results]—at least from the standpoint of those injured—would ostensibly consist of some sort of warning"); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 186 (5th Cir. 2012) ("Post-*Mensing*, . . . a seeming majority of federal district courts to consider other state-

law tort claims have found them to be preempted based on the fact that the plaintiffs' claims are failure-to-warn claims under different names.").

B. Negligent or Fraudulent "Off Label" Promotion Claims May Survive

Despite its unhesitating application of *Mensing* and *Bartlett* preemption to a wide variety of claims implicating the federal "duty of sameness" in the labeling and design of generic drugs, the Fifth Circuit has recently "decided not to decide" whether a claim for negligent or fraudulent ***off-label*** promotion of a generic drug can survive *Mensing* and *Bartlett* preemption. *See Whitener* v. *Pliva, Inc.*, No. 14-30468, 2015 U.S. App. LEXIS 5774, *10 (5th Cir. Apr. 9, 2015) (per curiam) (not designated for publication). The *Whitener* appellate court squarely recognized that "to the extent the Whiteners' claims were based on the defendants' affirmative promotion of metoclopramide for use during pregnancy [an off-label use], the district court was 'unwilling to conclude that such a claim fails as a matter of law.'" *Id.* at *4 (quoting *Whitener v. Pliva*, No. 10-1552 Section "L" (4), 2011 U.S. Dist. LEXIS 140053, *15 (E.D. Louisiana Dec. 6, 2011)). Nevertheless, the district court ultimately granted summary judgment on the grounds that the plaintiffs had failed to establish causation on this potential cause of action, and the Fifth Circuit "affirm[ed] the district court's dismissal of the Whiteners' claim . .. without reaching whether the Whiteners' off-label-promotion claim is a viable theory of recovery." *Id.* at *10.

The Fifth Circuit's non-decision is, to date, the only federal appellate decision addressing the effect of *Mensing* and *Bartlett* preemption on allegedly wrongful "off label" promotional activities. However, the *Whitener* district court decision, reasoning that negligent or fraudulent off-label promotional activities would not be preempted by the "duty of sameness," is in line with the opinions of several district courts to have considered the issue. For example, in *Arters v. Sandoz*, the United States District Court for the Southern District of Ohio specifically

considered the off-label promotion of amniodarone by Sandoz—the same generic drug and the same generic drug manufacturer before this court— and found that the plaintiffs' legal theories "based on the idea that defendants promoted the drug in a fraudulent or unreasonably dangerous way" for off label use would not be preempted by federal law, because "Nothing in the FDCA requires defendants to promote their drug for an off-label use, nor is the federal law otherwise at odds with the negligence, breach of implied warranty, and fraud claims brought by plaintiffs." 921 F. Supp. 2d 813, 819-20 (S.D. Ohio 2013).

Earlier this year, in the related context of medical device regulation, the District of Hawaii considered similar preemption arguments in *Beavers-Gabriel v. Medtronic*, No. 13-00686 JMS-RLP, 2015 U.S. Dist. LEXIS 2522 (D. Hawaii, Jan. 9, 2015). The court found no preemption where "Plaintiff's allegations are not directed to the Infuse Device's *labeling*—rather, Plaintiff asserts that Defendants failed to disclose relevant information regarding off-label uses of the Infuse Device to both the FDA and [plaintiff]." *Id.* (emphasis in original). A District Court in the Southern District of Texas may have put it best: "[T]he Court declines to find that any and all conduct that falls within the Plaintiffs' allegations of promoting Risperdal for ***off***-label uses in an illegal scheme necessarily fall within the concept of the regulation of labeling." *Elmore v. Gorsky*, No. 2:12-CV-00347, 2012 U.S. Dist. LEXIS 177793, *8-9 (S.D. Tex. Dec. 17, 2012) (emphasis in original). Thus, while it is clear under *Mensing* that Sandoz "has no mechanism to unilateral provide any additional warnings relevant to the off-label use" of its drugs, several courts have found "the *Mensing* analysis changes if a generic defendant *actively promotes* the drug for off-label use in violation of federal law." *Whitener v. Pliva*, No. 10-1552 Section "L" (4), 2012 U.S. Dist. LEXIS 127993, *6 (E.D. Louisiana, Sept. 10, 2012) (emphasis in original). The Fifth Circuit has declined to foreclose claims for wrongful off-label promotion,

despite its otherwise broad application of *Mensing* preemption. *Whitener*, 2015 U.S. App. LEXIS 5774, *10. It therefore appears that a claim for wrongful off-label promotion of a generic drug is potentially viable under current Fifth Circuit law. *Id.*

1. Elements of Wrongful "Off Label" Promotion Claims

Sandoz argues that, even if a claim for wrongful off-label marketing is not preempted, Plaintiffs have failed to plead it with sufficient specificity to survive a motion to dismiss. Mot. Dism. [#21] at 12-18. The *Whitener* district court decision is instructive in terms of what must be plead to establish a claim for wrongful off-label marketing (assuming such a claim exists.) 2011 U.S. Dist. LEXIS 140053, *16. "If Plaintiffs wish to pursue such a claim they should plead sufficient factual content regarding what marketing or promotional representations were made, by which Defendants, to whom, and how those statements violated applicable federal law." *Id.* [2]

2. Plaintiffs Should Be Granted Leave to Re-Plead This Claim

The Complaint as it stands alleges, *inter alia*:

- Rusk's specific amniodarone prescription was manufactured by Sandoz, Compl. at ¶ 49;
- Defendants, "respectively, jointly and severally" had actual and constructive knowledge of severe (including fatal) side effects from off-label uses of amniodarone, including the side effects suffered by Mr. Rusk, from direct reports of adverse advents to the manufacturer by the purchasing healthcare provider or end-user patient, or through the FDA's Adverse Event Reporting System (AERS). *Id.* at ¶¶ 86-88.

[2] On summary judgment, the Whitener plaintiffs failed to establish causation because, although they had identified specific acts of off-label promotion, they had failed to obtain deposition testimony or other evidence that these promotions caused the plaintiff's doctor to issue the off-label prescription. *Whitener*, 2015 U.S. App. LEXIS 5774, *10-12. Allegations of a "complex scheme to promote metoclopramide through congresses, doctors, and medical journals" was not substantiated by any evidence showing that the doctors "clinical judgment was *itself* influenced, in some indirect way, by the defendants' promotional activities." *Id.* (emphasis in original).

- Sandoz "and/or its agents' pharmaceutical sales representatives actively promoted their generic amniodarone in the stream of commerce for the 'off-label' uses openly promoted by Defendant Wyeth." *Id.* at ¶ 94.

- Defendants, "respectively, jointly, and severally, concealed information about catastrophic injuries and death, and thousands of serious adverse medical events from the FDA, health care professionals, and consumers, including Anthony Rusk." *Id.* at ¶ 97

- While Defendants "respectively, jointly and severally, concealed this adverse event information, they simultaneously engaged in a massive and fraudulent marketing and promotional scheme in which they aggressively and fraudulently promoted Cordarone®/amiodarone for uses never authorized by the FDA. In fact, Defendants marketed, promoted, and 'pushed' Cordarone®/amiodarone, not as a drug of last resort, but as a drug suitable as an initial therapy and to treat non-life-threatening heart conditions." *Id.* at ¶ 100.

- "Defendants' affirmative misrepresentations and omissions have so infected the market in the United States that physicians and consumers relied on Defendants' fraud, respectively, to the detriment of their patients and themselves." *Id.* at ¶ 107.

Sandoz contends these allegations are not specific enough to identify to whom or how Sandoz allegedly fraudulently marketed off-label use of amniodarone or concealed adverse events resulting from off-label use. Mot. Dism. [#21] at 17-18. The undersigned agrees. *See* FED. R. CIV. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.")

Plaintiffs have sought leave to amend their complaint. Resp. [# 27] at 2. Leave to amend should be freely granted, particularly where the circumstances suggest amendment would not be futile. FED. R. CIV. P. 15(a)(2). In this case, Plaintiff's claims for wrongful off-label promotion are not clearly foreclosed as a matter of law. *Whitener*, 2015 U.S. App. LEXIS 5774, *10. It is possible they will be able to amend their complaint to allege facts establishing both wrongful off-label promotion and reliance with the specificity required by Rule 9(b).

Should Plaintiffs wish to pursue this claim, they must amend their Complaint to identify, at a minimum, the promotional activities undertaken by agents or representatives of Sandoz to influence the specific physicians involved in Mr. Rusk's treatment to prescribe amniodarone off-label and/or the actions taken by agents or representatives of Sandoz to conceal from Mr. Rusk's physicians the risks associated with the off-label use of amniodarone in patients like Mr. Rusk. *See Whitener*, 2011 U.S. Dist. LEXIS 140053, *16; *see also Beavers-Gabriel*, 2015 U.S. Dist. LEXIS 2522, *16 (requiring that a complaint alleging fraudulent off-label promotion "include allegations making 'the connection between Defendants' alleged misdeeds and Plaintiff and Plaintiff's phyisicians—*i.e.*, that Plaintiff and Plaintiff's physicians relied on the misrepresentations.'") (quoting *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1038 (D. Hawaii 2014).

D. Failure to Supply FDA "Medication Guide" Claims May Survive

Despite rejecting a variety of allegedly parallel state tort claims as preempted by *Mensing* and *Bartlett*, the Fifth Circuit recently held in *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014) that an allegation that generic drug manufacturers "failed to provide [plaintiff] or his physician with any of the FDA-approved warnings . . .. would be a violation of both state and federal law, [and] this is a parallel claim that is not preempted." *Id.* at 679-80. Plaintiffs in this case allege that Defendant Sandoz was responsible for providing an FDA-mandated "Medication Guide." Compl. at ¶¶ 50, 54. Plaintiffs further allege that Mr. Rusk never received the Medication Guide, *id.* at ¶ 50, and that "the Pharmacies" assert "no manufacturer" was providing the Guides to pharmacists or patients. *Id.* at ¶ 137. To the extent Plaintiffs seek to allege that Sandoz failed to comply with its obligation to supply distributors with the FDA-required Medication Guides, and this failure proximately caused Mr. Rusk to take

amniodarone without knowledge of the FDA-approved warnings, such a claim would survive federal preemption under *Eckhardt*'s reasoning. 751 F.3d at 679.

1. Elements of Failure to Supply FDA Medication Guide Claim

Defendant Sandoz again asserts that, even if the alleged failure to supply a Medication Guide is viable as a matter of law, it has not been adequately alleged in this case. Mot. Dism. [#21] at 19. Recently, the District Court for the Northern District of Alabama considered what would be required to plead a claim for failure to provide an FDA-mandated Medication Guide. *Stevens v. Teva Pharmaceuticals*, No. CV-13-J-1357-NE, 2014 U.S. Dist. LEXIS 180568 (N.D. Alabama, Oct. 1, 2014). "Without a well-founded allegation that Huntsville Hospital Pharmacy [the pharmacy that filled the plaintiff's prescription] failed to provide a Medication Guide to Plaintiff because defendants did not supply the Guide to the pharmacy along with the medication, as required by 21 C.F.R. § 208.24, this claim cannot survive." *Id.* at *8.

2. Plaintiffs Should be Granted Leave to Re-Plead this Claim

Plaintiffs have generally alleged that unknown pharmacies have complained about not receiving Medication Guides from unknown manufacturers. Compl. at ¶ 137. There is no allegation in the Complaint, however, that the CVS that filled Mr. Rusk's prescription was unable to provide him a Medication Guide because Sandoz failed to supply one to CVS. *See Stevens*, 2014 U.S. Dist. LEXIS 180568 at *8. Therefore, Plaintiffs have not plead this claim with sufficient factual specificity to raise it above the level of "a sheer possibility that the defendant has acted unlawfully." *Id.* (citing *Iqbal*, 556 U.S. at 678). Because there is no suggestion that amendment of this claim would be futile, Plaintiffs should be granted leave to re-plead their claim for failure to provide a Medication Guide with the requisite specificity. FED. R. CIV. P. 15(a)(2).

IV. RECOMMENDATIONS

In accordance with the foregoing, the undersigned RECOMMENDS that Defendant's Motion to Dismiss [#21] be GRANTED WITHOUT PREJUDICE.

The undersigned further RECOMMENDS Plaintiffs' Motion for Leave to Amend be GRANTED. Specifically, the undersigned RECOMMENDS that Plaintiffs be granted leave to amend only their claims for wrongful off-label promotion and failure to supply adequate Medication Guides, as the remainder of their claims for relief "related to the manufacture, marketing, distribution, and sale of amniodarone," Compl. at ¶ 131, are preempted as a matter of law.

V. OBJECTIONS

The parties may file objections to this Report and Recommendation. A party filing objections must specifically identify those findings or recommendations to which objections are being made. The District Court need not consider frivolous, conclusive, or general objections. *See Battles v. United States Parole Comm'n*, 834 F.2d 419, 421 (5th Cir. 1987).

A party's failure to file written objections to the proposed findings and recommendations contained in this Report within fourteen (14) days after the party is served with a copy of the Report shall bar that party from de novo review by the District Court of the proposed findings and recommendations in the Report and, except upon grounds of plain error, shall bar the party from appellate review of unobjected-to proposed factual findings and legal conclusions accepted by the District Court. *See* 28 U.S.C. § 636(b)(1)(C); *Thomas v. Arn*, 474 U.S. 140, 150-53, 106 S. Ct. 466, 472-74 (1985); *Douglass v. United Services Automobile Ass'n*, 79 F.3d 1415 (5th Cir. 1996)(en banc).

To the extent that a party has not been served by the Clerk with this Report & Recommendation electronically, pursuant to the CM/ECF procedures of this District, the Clerk is ORDERED to mail such party a copy of this Report and Recommendation by certified mail, return receipt requested.

SIGNED June 11, 2015

MARK LANE
UNITED STATES MAGISTRATE JUDGE