UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

James E. McLeod and Glenda McLeod,	)	Civil Action No.: 4:16-cv-01640-RBH
Plaintiffs,	)	
v.	)	**ORDER**
Sandoz, Inc.,	)	
Defendant.	)	

This matter is before the Court on Defendant Sandoz, Inc.'s [ECF No. 6] motion to dismiss. For the reasons stated below, the Court grants in part and denies in part Defendant Sandoz, Inc.'s motion to dismiss.[1]

Factual[2] and Procedural Background

Plaintiffs, James E. and Glenda McLeod, filed their Complaint on May 23, 2016, alleging claims against Defendant Sandoz, Inc. for: 1) strict products liability - failure to warn; 2) negligence - failure to warn; 3) negligence - "off label" marketing and sale; 4) negligence *per se* - "off label" marketing/sale and failure to provide Medication Guide; 5) fraud and deceit; and 6) loss of consortium. The claims arise from Plaintiff James E. McLeod's use of the pharmaceutical drug amiodarone for treatment of his non-life threatening atrial fibrillation. Plaintiffs allege that after

[1] Under Local Civil Rule 7.08 (D.S.C.), "hearings on motions may be ordered by the Court in its discretion. Unless so ordered, motions may be determined without a hearing." Upon review of the briefs, the Court finds that a hearing is not necessary.

[2] When reviewing a motion made under Federal Rule of Civil Procedure 12(b)(6), the court must "accept all well-pleaded allegations in the plaintiff's complaint as true and draw all reasonable factual inferences from those facts in the plaintiff's favor." *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir. 1999). Accordingly, the Court will assume the facts alleged in the Complaint are true for purposes of resolving the pending motion to dismiss.

ingesting amiodarone, which was manufactured by Defendant Sandoz, Inc. ("Sandoz"), McLeod developed and was diagnosed with shortness of breath and chronic obstructive and progressive pulmonary disease. [Complaint, ECF No. 1, at ¶ 18]. The amiodarone tablets were manufactured and sold by Sandoz as a generic version of Wyeth's Cordarone®.

In 1985, brand manufacturer Wyeth (who is not a party to this litigation) received FDA approval to market and sell the anti-arrhythmic heart medication Cordarone® (amiodarone hydrochloride) under a special "needs" approval without the usual FDA approved, double-blind, randomized clinical trials. *Id*. at ¶ 29. The customary and rigorous randomized clinical trials now required by the FDA for all new drug applications have never been conducted for Cordarone® or its generic equivalent, amiodarone. *Id*.

The FDA approved Cordarone® (amiodarone hydrochloride) only 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. *Id*. at ¶ 30. Plaintiffs allege Wyeth, however, aggressively and successfully marketed Cordarone® for inappropriate "off label" uses as a "first line anti-arrhythmic therapy." *Id*. Generally, Plaintiff alleges he was not in a situation of last resort as to the management of his atrial fibrillation.

Plaintiffs contend Wyeth also instituted and maintained an active promotional campaign touting the anti-arrhythmic benefits of amiodarone, from which generic manufacturers such as Sandoz still benefit. *Id*. at ¶ 31. As a result of Wyeth's off-label promotion, amiodarone became a first line therapy for atrial fibrillation because physicians were not warned of many of the potential dangers of the drug. *Id*. Wyeth's alleged fraudulent and misleading marketing campaigns resulted in

warning letters from the FDA to stop the false and misleading promotion of the drug that downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy. *Id*. The FDA letters noted it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug. *Id*. Unapproved uses are deemed "off-label" because they have not been approved by the FDA. *Id*.

In 1998, Wyeth received approval for the manufacture, marketing, sale and distribution of the generic formulation of Cordarone®, amiodarone hydrochloride. *Id*. at 32. Plaintiffs assert Defendant Sandoz took advantage of the pervasive promotional activities of Wyeth and allege that Sandoz's version of the drug directly benefited from Wyeth's marketing of the drug for "off-label" uses. *Id*.

Sandoz was required to provide patients prescribed amiodarone with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand formulation manufacturer, Wyeth. *Id*. at ¶ 33. The Medication Guide for amiodarone outlined serious side effects, such as lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. *Id*. at ¶ 39.

Before being prescribed amiodarone, Plaintiff James McLeod was diagnosed with atrial fibrillation that was not deemed life threatening. *Id*. at ¶ 34. The management of McLeod's atrial fibrillation was not considered a medical situation of "last resort." *Id*.

Beginning in June of 2014 and continuing through November 2015, McLeod was prescribed a course of 200 mg amiodarone tablets for treatment of his non-life threatening atrial fibrillation. *Id*. at ¶ 35. McLeod was not aware that his use of amiodarone was for an "off-label" use and he did not

receive the required Medication Guide from Sandoz. *Id*. Correction of atrial fibrillation and any use except in situations of last resort were never FDA approved uses of Cordarone® or its generic equivalents. *Id*. McLeod's prescription was for an "off-label" use and without the benefit of the FDA mandated Medication Guide. *Id*.

The prescription for the amiodarone tablets was marked with the numbers 00185-0144-60 and was manufactured by Sandoz. *Id*. at ¶ 36. Plaintiffs allege the "off-label" prescription and distribution of the drug to control a non-life threatening atrial fibrillation, also a direct result of the long term promotional efforts of Sandoz and without the required Medication Guide, was a producing and proximate cause of James McLeod's physical condition and injuries from amiodarone toxicity. *Id*. Plaintiffs allege that if McLeod had received the Medication Guide, he would have been aware of the serious lung related side effects and would not have taken amiodarone. *Id*. at ¶¶ 38-39.

In the fall of 2014-2015, McLeod began to experience many of the symptoms outlined in the Medication Guide including shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. *Id*. at ¶ 44. McLeod's condition continued to deteriorate and in March of 2015, he was admitted to McLeod Regional Medical Center with severe shortness of breath. In October 2015, McLeod was diagnosed with COPD. *Id*. at ¶ 46.

Plaintiffs allege Sandoz received direct notice of adverse events resulting from the use of amiodarone including pulmonary toxicity, pulmonary fibrosis, lung damage, hepatic damage and failure, neurotoxicity, peripheral neuropathy, neonatal hypothyroidism, optic neuritis, toxic optic neuropathy, blindness, serious exacerbation of arrhythmias, and congestive heart failure such as that

experienced by McLeod. *Id*. at ¶ 49. Plaintiffs assert Sandoz failed to disclose to the FDA, healthcare professionals, consumers, or McLeod information concerning the incidents and actual adverse events, injuries, and deaths suffered by amiodarone users. *Id*. at ¶ 53.

Plaintiffs also allege Sandoz took advantage of the promotional efforts of Wyeth for "off-label" uses, in addition to its own efforts, including the following:

a) Direct-to-physician and direct-to-pharmacist promotion through sales representatives;

b) Promotion through funding and manipulation of so-called "educators" who organize and arrange continuing medical education (CME) courses for physicians and pharmacists;

c) Formulation of unlawful conspiracies with certain medical marketing and medical "education" entities to promote – without appearing to promote – "off-label" uses;

d) Sponsorship and funding of the production of CME materials;

e) Cultivation and development of so-called "opinion leaders" in local medical communities and support for the careers and research of those physicians, pharmacists, and researchers who advocate off-label uses;

f) Sponsorship of journal supplements and symposia on "off-label" uses;

g) Placing (through sponsorship of limited trials, studies, and surveys) of medical literature databases showing positive effects (already established) on risk factors with the twin purposes of overwhelming any independent study showing negative effects on different risk factors, and causing earnest but

time-crunched physicians to be impressed with the sheer quantity of favorable (but redundant) studies on MedLine, or medical library, search;

h) Media advertisements and brochures, some of which were disguised as "educational materials";

i) Coordination of physician-to-physician interactions that are biased toward "off-label" usages;

j) Internet listings that omit important warnings and information; and

k) Various other forms of marketing and promotion.

Id. at ¶ 53. Despite FDA warnings and thousands of adverse patient experiences, Sandoz continued their alleged fraudulent marketing, promotional, and sales practices. *Id*. at ¶ 56.

Plaintiffs allege the amiodarone manufactured and/or supplied by Sandoz was not accompanied by proper warnings regarding all possible adverse side effects and comparative severity and duration of such side effects. *Id*. at ¶ 58. Plaintiffs further allege the amiodarone manufactured, distributed, and/or supplied by Sandoz was defective due to inadequate post-marketing warning and instruction because, after Sandoz knew or should have known of the risk of injury from amiodarone, especially in "off-label" use, Sandoz failed to provide adequate warnings to physicians and consumers, including Plaintiff McLeod, and continued to aggressively sell amiodarone for "off-label" use. *Id*. at ¶ 61. Plaintiffs contend the warnings for amiodarone were vague, incomplete, and/or otherwise wholly inadequate. *Id*. at ¶ 67.

Plaintiffs allege Sandoz owed a duty to engage in honest and non-deceptive practices; exercise due care under the circumstances; exercise due care in the design, manufacture, marketing, promotion, sale, and distribution of amiodarone; to provide a reasonably safe and non-defective

drug; to provide adequate and appropriate warnings; to comply with federal guidelines; and/or to sell and distribute the drug in accordance with FDA restrictions. *Id.* at ¶ 69.

Plaintiffs filed their Complaint on May 23, 2016, alleging claims for: 1) strict products liability - failure to warn; 2) negligence - failure to warn; 3) negligence - "off label" marketing and sale; 4) negligence *per se* - "off label" marketing/sale and failure to provide Medication Guide; 5) fraud and deceit; and 6) loss of consortium. Plaintiffs seek compensatory and exemplary damages, applicable interest, costs, attorney's fees and all such other relief the Court deems proper.

Sandoz responded with the pending motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure arguing that each of Plaintiffs' claims are preempted by federal law and should be dismissed. Sandoz also argues Plaintiffs' fraud claim fails to meet the heightened pleading requirements of Fed. R. Civ. P. 9(b) and their off-label promotion claims fail in light of the learned intermediary doctrine that applies to prescription drug manufacturers. Sandoz further argues that Plaintiffs' Medication Guide claim fails under the learned intermediary doctrine and also because there is no private right of action for failure to provide a Medication Guide. Sandoz further maintains that the duty to provide the Medication Guide to Plaintiff McLeod fell upon the CVS or Walgreens pharmacies that dispensed the drug, not Sandoz. Finally, Sandoz argues that because all of Plaintiff James McLeod's claims are either preempted or insufficiently pled, Plaintiff Glenda McLeod's loss of consortium claim also fails.

Rule 12(b)(6) Standard

When deciding a motion to dismiss made under Federal Rule of Civil Procedure 12(b)(6), the Court must accept all well-pled facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250,

253 (4th Cir. 2009). A complaint must state a "plausible claim for relief" to survive a 12(b)(6) motion to dismiss. *Walters v. McMahen*, 684 F.3d 435, 439 (4th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). The Court will not dismiss the plaintiff's complaint so long as he provides adequate detail about his claims to show he has a "more-than-conceivable chance of success on the merits." *Owens v. Baltimore City State's Attorneys Office*, 767 F.3d 379, 396 (4th Cir. 2014) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Twombly*, 550 U.S. at 563. A complaint will survive a motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." *Id*. at 570. However, when a plaintiff's assertions "amount to nothing more than a 'formulaic recitation of the elements' " of a cause of action, the Court may deem such allegations conclusory and not entitled to an assumption of veracity. *Iqbal*, 556 U.S. at 681 (quoting Twombly, 550 U.S. at 555).

Discussion

I. Federal Preemption

A. *Mensing* and *Bartlett* Preemption

Sandoz argues that because each of Plaintiffs' claims is essentially a failure to warn or design defect claim, each claim is preempted pursuant to the Supreme Court cases *PLIVA Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466, 2470, 186 L.Ed.2d 607 (2013). *Mensing* and *Bartlett* address the preemptive effect of the Food, Drug, and Cosmetic Act ("FDCA") on state tort laws as they apply to generic drug manufacturers.

Under the Hatch–Waxman amendments, codified at 21 U.S.C. § 355(j), the FDCA imposes substantially different requirements on producers of name brand drugs and producers of

non-branded, or generic, counterparts. Manufacturers of generic medications gain authorization to market their products by demonstrating that those products are equivalent to the previously authorized name brand versions in a number of ways, including formulation and labeling. Generic drug manufacturers must maintain this equivalence to maintain authorization. *See* 21 U.S.C. § 355(j). In other words, the FDCA and its related regulations limit a generic drug manufacturer's ability to attach additional warnings to their drug. While brand companies are free to unilaterally disseminate additional information about their drugs-including updated warnings and instructions for use – through direct correspondence to healthcare providers, generic drug companies may not. "Federal law ... demand[s] that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Mensing*, 564 U.S. at 618. In fact, "changes unilaterally made to strengthen a generic drug's warning label would violate the [federal law]." *Id*. at 614.

In *Mensing*, the Supreme Court made clear that under § 355(j) generic drug manufacturers are not entitled to unilaterally change their labeling and therefore any state law tort premised on the failure of a generic to alter its labeling is preempted. *Id*. at 618. In *Bartlett*, the Supreme Court emphasized that generics are also not permitted to change the formulation of their products. 133 S.Ct. at 2471, 2475. Further, the Court rejected the argument that a generic drug manufacturer is required to leave the marketplace in order to avoid state law liability resulting from its inability to change either its labeling or formulation. *Id*. at 2477. Stated another way, courts may not avoid preempting a state law by imposing liability on a generic manufacturer for choosing to continue selling its product. Together, these cases establish that under the FDCA a generic may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability for its failure to change its labeling, design, or formulation.

Plaintiffs respond that *Mensing* and *Bartlett* do not apply because their claims do not challenge the adequacy or "content" of the warning label, but rather challenge Sandoz's alleged "off-label" marketing and alleged failure to provide a Medication Guide to McLeod. Plaintiffs' claims appear to be premised on the notion that the warnings contained within the Medication Guide were adequate.[3] Yet, Plaintiffs' complaint also alleges "the warnings for amiodarone, in effect during the relevant time period were vague, incomplete, and/or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians, pharmacists, consumer patients and McLeod of the actual risks associated with this drug." [ECF No. 1, Complaint at ¶ 67]. Plaintiff further alleges:

> At all material times, the amiodarone, manufactured and/or supplied by Defendant was and is unaccompanied by proper warnings regarding all possible adverse side effects and comparative severity and duration of such adverse effects; the warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. This is particularly so with regard to "off-label" use. . . .
>
> At all material times, the amiodarone manufactured, distributed, and/or supplied by Defendant was defective due to inadequate post-marketing warning and instruction because after Defendant knew or should have know of the risk of injury from amiodarone, especially in "off-label" use, Defendant failed to provide adequate and required warnings to physicians, users or consumers of amiodarone. . .
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> The warnings and directions provided with amiodarone by Defendant failed to adequately warn of the potential risks and side

[3] Plaintiffs' Complaint alleges: "Had the Medication Guide been provided by Sandoz to the distributor or his pharmacist for distribution to him as required by FDA regulations, McLeod would have been aware of the serious lung related side effects that would lead to his physical condition and injuries . . . McLeod would not have taken amiodarone and would not have incurred the serious and life threatening injuries had he received the required Medication Guide." [ECF No. 1, Complaint at ¶ 38].

> effects of amiodarone and the dangerous propensities of said medication, which risks were known or were reasonably scientifically knowable to Defendant when, among other things, they failed to ensure the Medication Guide was provided to all consumers, including Plaintiff.

Id. at ¶¶ 58, 61 & 92. Plaintiffs do not address this apparent inconsistency in their briefs and appear to have abandoned any claims regarding the adequacy or content of the warnings for amiodarone. However, to the extent those claims are not abandoned, they are due to be dismissed as preempted under *Mensing* and *Bartlett* because Sandoz could not have changed the content of the warning labels or Medication Guide and could not have disseminated additional warnings regarding "off-label" use without violating federal law.

Separate and apart from the Medication Guide claims, the Court questions whether Plaintiffs' "off-label" promotion claims can survive the preemption analysis under *Mensing* and *Bartlett*. Plaintiffs argue that their "off-label" promotion claims are not preempted under *Mensing* and *Bartlett* because the claims do not challenge the adequacy or content of the manufacturer's warning for amiodarone. In the Court's view, Plaintiffs' claims have a tendency to do exactly that. The basis for Plaintiffs' "off-label" marketing claims is that Sandoz, by virtue of its marketing of amiodarone for first line non-life threatening atrial fibrillation treatment instead of "last resort" treatment, rendered the manufacturer's warning inadequate. If Plaintiffs' "off-label" claims are successful, in order to avoid future liability Sandoz could arguably be required to either: 1) change the warning label or disseminate additional warnings to reflect the alleged additional dangers associated with the "off-label" use of amiodarone for atrial fibrillation; or 2) exit the market place. Such a result requires preemption under *Mensing* and *Bartlett*. However, as noted in *Whitener v. PLIVA, Inc.*, 2012 WL 1995795, at *4 (E.D. La. June 4, 2012), "there is something troubling about

permitting a generic defendant to violate federal law by actively and aggressively promoting a drug for a purpose not contemplated by the label approved by the FDA while also hiding behind an inability to provide warnings connected to that off-label use because it cannot change the approved label." The Court also notes that no circuit court of appeals to date has held that "off-label" promotion claims are preempted under *Mensing* and *Bartlett*. At this early stage of the case, the Court declines to hold that Plaintiffs' "off-label" promotion claims are nothing more than preempted failure to warn claims.

B. *Buckman* Preemption

With regard to Plaintiffs' claims related to "off-label" promotion and the failure to provide a Medication Guide - claims that, according to Plaintiffs, do not challenge the adequacy or content of the warning label for amiodarone, Sandoz argues that because those claims are premised solely upon federal duties, and there is no private right of action to enforce those federal duties, Plaintiffs' claims for "off-label" promotion and failure to provide a Medication Guide are impliedly preempted under *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and 21 U.S.C. § 337(a).

1. "Off-label" Promotion

At the outset, it should be noted that Plaintiffs advance "off-label" promotion claims based on both fraud and negligence theories. Because the claims are based on different theories of recovery, they require different treatment. As explained more fully below, Plaintiffs' negligent "off-label" promotion claim is preempted under *Buckman* and 21 U.S.C. § 337(a) because it is premised solely upon duties set forth in the FDCA and applicable regulations and there are no parallel South Carolina state tort remedies for the negligent "off-label" promotion of generic drugs. Plaintiffs' fraudulent "off-label" promotion claim, premised on Sandoz's obligations under state fraud law to

refrain from falsely promoting their drugs for unapproved uses, is not preempted.

The FDCA does not provide a private right of action for a defendant's violation of its provisions. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 810 (1986). Instead, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Accordingly, where "the existence of these federal enactments is a critical element in [plaintiff's] case," and where a plaintiff's claims "exist solely by virtue of the FDCA ... requirements," state law claims are impliedly preempted by the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Where, by contrast, a plaintiff's claims rest on "traditional state tort law principles of the duty of care," the establishment of which "predated the federal enactments in question," a plaintiff may bring a state law claim for conduct also in violation of the FDCA. *Id*. *Buckman* does not extend so far as to restrict "certain state-law causes of actions that parallel federal safety requirements." *Id*.; *see Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1339 (10th Cir. 2015) ("*Buckman* left undisturbed ... state lawsuits based on 'traditional state tort law' that 'predate[s]' the FDCA but happens to 'parallel' it.").

Under *Buckman*, "[f]or a state-law claim to survive, ... the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Williams v. Smith & Nephew, Inc.*, 123 F.Supp.3d 733, 746 (D. Md. 2015) (quotations omitted); *see Evans v. Rich*, No. 5:13–CV–868–BO, 2014 WL 2535221, at *2 (E.D.N.C. June 5, 2014) ("The test for determining whether a state law claim is impliedly preempted is whether or not the claim would exist in the absence of the FDCA."); *Loreto v. Procter & Gamble Co.*, 515 Fed.Appx. 576, 579 (6th Cir.2013) ("If the claim would not exist in the absence of the FDCA, it is impliedly preempted."); *see also In re Medtronic, Inc., Sprint Fidelis Leads*

Products Liab. Litig., 623 F.3d 1200, 1204 (8th Cir.2010) (recognizing "a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption[:] ... the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).") (quotations omitted).

In this case, Plaintiffs' claims of negligence and negligence per se based on the alleged "off-label" promotion of amiodarone are impliedly preempted under *Buckman* because the duties Plaintiffs allege Sandoz breached regarding "off-label" promotion exist solely under the FDCA. For instance, Plaintiffs allege:

> Defendant owed a duty to Plaintiff to market and sell amiodarone for uses approved by the FDA and for uses for which it has been established as efficacious and safe.
>
> Defendant, as the manufacturer, designer and marketer of amiodarone, owed a duty of care to Plaintiff and other consumers of amiodarone to ensure it marketed and sold it only for approved uses. Instead, Defendant engaged in a campaign to market the drug for "off-label" uses, in particular for the treatment of atrial fibrillation.
>
> Defendant owed a duty to Plaintiff to market and sale [sic] amiodarone only for uses approved by the FDA and for uses for which it has been established as efficacious and safe.
>
> Defendant violated this duty by marketing, promoting and selling amiodarone for uses not approved by the FDA.

[Complaint at ¶¶ 105, 106, 112, and 113, ECF No. 1]. Plaintiff has not directed the Court to any S.C. state law causes of action that parallel the federal safety requirements limiting the "off-label" promotion of drugs. Plaintiffs' claim for the negligent "off-label" promotion of amiodarone would not exist in the absence of the FDCA. Accordingly, Plaintiffs' claim for negligence and negligence per se based on Sandoz's alleged "off-label" promotion of amiodarone for atrial fibrillation is

impliedly preempted under *Buckman* and due to be dismissed. *See, e.g. Perdue v. Wyeth Pharms., Inc.*, __ F. Supp. 3d __, 2016 WL 3951091, at *5 (E.D.N.C. 2016) (dismissing plaintiff's claim for negligent "off-label" promotion of amiodarone because the claim was not premised on conduct that would give rise to a recovery under state law in the absence of the FDCA).

By contrast, Plaintiffs' fraud claim related to the promotion and marketing of amiodarone is not preempted under *Buckman*. Plaintiffs' fraud claim is premised on state common law fraud that predates the FDCA. *See, e.g., Tallevast v. Herzog*, 83 S.E.2d 204, 206-07 (S.C. 1954); *Jones v. Cooper*, 109 S.E.2d 5, 7 (S.C. 1959). State laws traditionally prohibit fraud and deceit in advertising and marketing. Plaintiffs essentially allege that Sandoz misrepresented the safety and efficacy of amiodarone and falsely promoted the drug for unapproved uses. [Complaint at ¶¶ 116-129]. Plaintiffs further allege:

> Defendant misled Plaintiff, Plaintiff's physician, and the public into believing that amiodarone was safe and effective for use in the treatment of atrial fibrillation, and engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals and patients to use amiodarone . . ., even though Defendants knew or should have known that amiodarone was unreasonably unsafe.
>
> Defendant's advertising program and promotional items, by containing affirmative misrepresentations and omitting material facts, falsely and deceptively sought to create the image and impression that amiodarone was safe for human use, had no unacceptable side effects, and would not interfere with daily life.
>
> Defendant's advertising program and promotional items, by containing affirmative misrepresentations and omitting material facts, falsely and deceptively sought to create the image and impression that amiodarone was safe for human use, had no unacceptable side effects, and would not interfere with daily life.
>
> Defendant actively concealed, failed to disclose, misstated,

downplayed and understated the health hazards and risks associated with the use of amiodarone. Defendant, through their promotional practices, deceived potential treating physicians, Plaintiff, other patients, and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiff, regarding the safety of amiodarone in terms of its "off-label" use.

Defendant expressly denied that amiodarone created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from amiodarone in terms of its "off-label" use.

Defendant did not accurately report the results of adverse events by withholding from the FDA, physicians, Plaintiff, and the public, the truth regarding amiodarone failures for years, all the while undertaking a major advertising campaign to sell amiodarone. Defendant received reports of amiodarone's side effects attributable to "off-label" use from various sources, and withheld this information and maintained it in their possession, while continuing to sell amiodarone to individuals such as Plaintiff.

Defendant effectively deceived and misled the scientific and medical communities regarding the risks and benefits of amiodarone. Defendant failed to fully inform physicians, patients, including Plaintiff, and the public of the true defects in amiodarone, which were known to Defendant, and continued to assure physicians and patients that amiodarone was adequate and reliable for the purpose intended and continued to continue to sell amiodarone.

Through the materials they disseminated, Defendant falsely and deceptively misrepresented or omitted a number of material facts regarding amiodarone as set forth in detail above.

Defendant possessed evidence demonstrating amiodarone caused serious adverse side effects. Nevertheless, Defendant continued to market amiodarone by providing false and misleading information with regard to its safety to Plaintiff and Plaintiff's treating physician.

Among Defendant's numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's physician and the general public

> are Defendant's assurances that amiodarone was a safe and effective drug for the treatment of atrial fibrillation. Defendant made such statements even after they became aware of numerous and serious complications with amiodarone. Defendant did not reveal (and instead actively concealed) their knowledge of numerous and serious complications with amiodarone. Despite their knowledge of serious problems with amiodarone, Defendant continued and continue to market amiodarone.
>
> Defendant also concealed from Plaintiff and Plaintiff's physician the material facts they were obligated to disclose, including that amiodarone was not FDA approved for the treatment of atrial fibrillation, was not an appropriate "first line of treatment" for atrial fibrillation, is required to be accompanied by a Medication Guide intended to warn the consumer of the serious, life-threatening complications from the use of amiodarone and was approved by the FDA for limited use without any associated clinical trials establishing the safety and efficacy of the drug.

Id. at ¶¶ 117-126. Sandoz's alleged fraudulent conduct, as set forth in Plaintiffs' Complaint, would give rise to recovery even in the absence of the FDCA. Therefore, Plaintiffs' fraud claim based on the promotion and marketing of amiodarone is not preempted under *Buckman*.

2. Medication Guide

Plaintiffs also assert failure to warn and negligence claims based on Sandoz's alleged failure to provide a Medication Guide with Plaintiffs' prescription of amiodarone. The duty to provide a Medication Guide exists solely under the FDCA and its applicable regulations. *See* 21 U.S.C. § 355(j)(2)(A)(v) & 355(j)(4)(G))) and 21 C.F.R. § 208.24. Specifically, 21 C.F.R. § 208.24 provides that "[e]ach manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients." Because the requirement to provide a Medication Guide to distributors is based solely in the requirements of the FDCA and related regulations, and there is no parallel duty

to provide a Medication Guide under South Carolina law, Plaintiffs' claims based upon failure to provide a Medication Guide are preempted under *Buckman*. *See Perdue*, 2016 WL 3951091, at *5. Stated another way, Plaintiffs' claims against Sandoz for failure to provide a Medication Guide are preempted and due to be dismissed because the claims would not exist in the absence of the FDCA.[4]

II. Learned Intermediary Doctrine

Sandoz argues that Plaintiffs' claims related to "off-label" promotion fail under the learned intermediary doctrine because Plaintiffs have not alleged that the prescribing physicians would have changed their prescribing decisions had different or additional warnings accompanied amiodarone, and have not alleged that McLeod's prescribing physicians relied upon any representations or statements by Sandoz. Plaintiffs did not respond to Sandoz's learned intermediary doctrine argument and, importantly, do not argue that the learned intermediary doctrine does not apply.[5]

Although there is no South Carolina Supreme Court case specifically adopting the learned intermediary doctrine in the context of pharmaceutical drug or device litigation, the Fourth Circuit Court of Appeals has predicted that the South Carolina Supreme Court would adopt the doctrine if presented with the issue. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir.1992). Under the learned intermediary doctrine,

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[4] Plaintiffs' Medication Guide claims are also due to be dismissed because, pursuant to the learned intermediary doctrine, the manufacturer's duty to warn only extends to the prescribing physicians, not the patient. *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir.1992); *Sauls v. Wyeth Pharms., Inc.*, 846 F. Supp. 2d 499, 504 (D.S.C. 2012); *Dreher v. Wyeth Pharms, Inc.*, No. 2:14-cv-00280-KOB, 2015 WL 3948961, at *8 (N.D. Ala. June 29, 2015).

[5] Plaintiffs' failure to respond to the learned intermediary argument is striking because Plaintiffs' counsel has been involved in several other amiodarone cases that were dismissed in part pursuant to the learned intermediary doctrine. *See, e.g. Stephens v. Teva Pharms., U.S.A., Inc.*, 70 F. Supp. 3d 1246, 1254 (N.D. Ala. 2014); *Allain v. Wyeth Pharms., Inc.*, No. 2:14-cv-00280-KOB, 2015 WL 178038, at *6 (N.D. Ala. Jan. 14, 2015); *Connolly v. Sandoz Pharms. Corp.*, No. 2:14-cv-152-WCO, 2014 WL 12480025, at *5 (N.D. Ga. Dec. 23, 2014).

"the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device." *Odom*, 979 F.2d at 1003. The manufacturer of a drug has a duty to warn the patient's doctor who acts as a "learned intermediary" between the patient and the manufacturer. The rationale behind this doctrine is the doctor is in a better position to warn the patient than the manufacturer. In a prescription drug case, a plaintiff must not only show that the drug manufacturer's warning was inadequate, but "also establish that the inadequacy of the warning was the proximate cause of the plaintiff's injury." *Sauls*, 846 F. Supp. 2d at 502 (citing *Stanback v. Parke, Davis, & Co.*, 657 F.2d 642, 645 (4th Cir.1981)). In light of the learned intermediary doctrine, "the burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Odom*, 979 F.2d at 1003.

Plaintiffs alleged:

> Defendant actively concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of amiodarone. Defendant, through their promotional practices, deceived potential treating physicians, Plaintiff, other patients, and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiff, regarding the safety of amiodarone in terms of its "off-label" use.
>
> Defendant expressly denied that amiodarone created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from amiodarone in terms of its "off-label" use.
>
> Defendant did not accurately report the results of adverse events by withholding from the FDA, physicians, Plaintiff, and the public, the truth regarding amiodarone failures for years, all the while undertaking a major advertising campaign to sell amiodarone. Defendant received reports of amiodarone's side effects

> attributable to "off-label" use from various sources, and withheld this information and maintained it in their possession, while continuing to sell amiodarone to individuals such as Plaintiff.

[Complaint at ¶¶ 119-121, ECF No. 1]. Plaintiffs further allege Defendant "misled Plaintiff, Plaintiffs' physician, and the public into believing that amiodarone was safe and effective for use in the treatment of atrial fibrillation, and engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals and patients to use amiodarone." *Id*. at ¶ 117.

Although Plaintiffs have alleged that Sandoz misled McLeod's prescribing physicians into believing that amiodarone was safe and effective for use in the treatment of atrial fibrillation, Plaintiffs have not alleged that McLeod's prescribing physicians would have changed their prescribing decision had different or additional warnings accompanied amiodarone. Of course, to the extent Plaintiffs claim that different or additional warnings should have accompanied amiodarone with regard to its "off-label" use, those claims against a generic drug manufacturer would be clearly preempted under *Mensing* and *Bartlett* because Sandoz could not change the FDA approved warnings for amiodarone.

The application of the learned intermediary doctrine to Plaintiffs' "off-label" promotion claims exposes a conceptual flaw in Plaintiffs' case. To avoid preemption under *Mensing* and *Bartlett*, Plaintiffs state they do not challenge the adequacy or content of the FDA approved warnings for amiodarone. To support their Medication Guide claim, Plaintiffs also contend the Medication Guide adequately set forth the risks associated with amiodarone and if Plaintiff McLeod had received the Medication Guide, he would not have taken amiodarone. [Complaint at ¶ 38, ECF No. 1]. Yet, in order to overcome the learned intermediary doctrine in this case, Plaintiff McLeod's

prescribing physicians would essentially have to testify that they were unaware of a risk that Plaintiffs allege was adequately disclosed in the Medication Guide for amiodarone. Critically, Plaintiffs have not alleged that the prescribing physicians did not receive the Medication Guide or were otherwise unaware of its contents.

Plaintiffs have not alleged that McLeod's prescribing physicians were unaware of the contents of the Medication Guide or the risk of pulmonary toxicity or lung problems possibly resulting in death. Further, Plaintiffs have not alleged that the prescribing physicians would have changed their decision to prescribe amiodarone had they been aware of the risk of pulmonary toxicity or lung problems possibly resulting in death. Plaintiffs have failed to state a claim to relief that is plausible on its face as Plaintiffs have not pled facts sufficient to establish causation in light of the learned intermediary doctrine. *See, e.g. Luberda ex rel. Luberda v. Purdue Frederick Corp.*, No. 4:13-cv-00897-RBH, 2014 WL 1315558, at *6 (D.S.C. March 28, 2014).

The Court considered dismissing Plaintiffs' fraudulent "off-label" promotion claim without prejudice on the basis of the learned intermediary doctrine; however, Plaintiffs have asked to amend their complaint and it is not clear to the Court whether dismissal without prejudice would create issues for Plaintiffs regarding the statute of limitations. To be clear, Plaintiffs' "off-label" promotion claim premised on negligence and negligence per se is dismissed with prejudice because that claim is preempted under *Buckman*. Plaintiffs' "off-label" promotion claim based on fraud may proceed if Plaintiffs can amend their fraudulent "off-label" promotion claim to state facts sufficient to establish causation in light of the learned intermediary doctrine. *See Luberda*, 2014 WL 1315558, at *6 (allowing amendment of complaint to plead facts in accordance with the learned intermediary doctrine). If Plaintiffs elect to amend their fraudulent "off-label" promotion claim, they should be

mindful of the specificity requirements for fraud claims under Rule 9(b) of the Federal Rules of Civil Procedure.

Conclusion

For the reasons stated above, Defendant Sandoz, Inc.'s [ECF No. 6] motion to dismiss is **GRANTED in part and DENIED in part**. Specifically, Plaintiffs' first, second, third, fourth, and sixth causes of action are **DISMISSED with prejudice**. The Court **DENIES without prejudice** Sandoz's motion to dismiss Plaintiffs' fifth cause of action (fraudulent "off-label" promotion) and seventh cause of action (loss of consortium based on fraudulent "off-label" promotion). Plaintiff shall file an amended complaint regarding Plaintiffs' fifth and seventh causes of action within fifteen (15) days of the entry of this Order.

IT IS SO ORDERED.

March 31, 2017
Florence, South Carolina

s/ R. Bryan Harwell
R. Bryan Harwell
United States District Judge