IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
EASTERN DIVISION

NO. 4:15-CV-208-FL

SARA G. PERDUE, as Executor of the Estate of Marjorie S. Newton, Deceased, Plaintiff, v. WYETH PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; BARR LABORATORIES, INC.; and ZYDUS PHARMACEUTICALS USA, INC., Defendants.	)	ORDER

This matter comes before the court on defendants' motions to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (DE 23, 34, 41). Plaintiff has responded in opposition, and defendants have replied. In this posture, the issues raised are ripe for ruling. For the following reasons, defendants' motions are granted.

STATEMENT OF THE CASE

Plaintiff commenced this action on December 28, 2015, asserting state law claims for wrongful death premised upon defendants' allegedly fraudulent and negligent actions in promoting a drug under the name Cordarone®/amiodarone for off-label use, failing to adequately inform of dangers thereof, and failing to provide a medication guide to distributors. Defendant Wyeth Pharmaceuticals, Inc., ("Wyeth"), which manufactures brand-name Cordarone®, moved to dismiss all claims against it on February 2, 2016. Defendants Barr-Laboratories, Inc. ("Barr"), Teva

Pharmaceuticals USA, Inc. ("Teva"), and Zydus Pharmaceuticals USA, Inc. ("Zydus") (collectively, the "generic defendants"), which manufacture generic amiodarone, filed motions to dismiss all claims against them on February 29 and March 10, 2016. On March 18, 2016, the court denied plaintiff's motion to stay the case pending consideration of transfer for multidistrict litigation. On June 2, 2016, the court received a copy of an order by the United States Judicial Panel on Multidistrict Litigation denying transfer to multidistrict litigation.

STATEMENT OF FACTS

The facts alleged in the complaint may be summarized as follows. Defendant Wyeth manufactures, promotes, and sells Cordarone®, which the Food and Drug Administration (FDA) approved in 1985 as a drug for use in "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. ¶33). Defendant Wyeth has promoted Cordarone® for use in controlling atrial fibrillation, which is a use not described in the FDA-approved labeling for the drug, thus constituting an "off-label" use. (Id. ¶34). The generic defendants manufacture, promote, and sell amiodarone, a generic formulation of Cordarone® that the FDA approved in 1998. The generic defendants also promote amiodarone for the off-label use in controlling atrial fibrillation.

Marjorie S. Newton ("Newton") was plaintiff's mother. In 2006, Newton's doctor diagnosed Newton with atrial fribrillation not deemed life threatening, and prescribed Newton a course of 200mg amiodarone tablets. Newton filled the prescription at Realo Discount Pharmacy, with tablets manufactured, marketed, and distributed by the generic defendants. Newton was not aware that her doctor prescribed her amiodarone for an off-label use. Newton did not receive with her prescription

a medication guide, which federal statute requires generic drug manufacturers to provide to drug distributors. Newton was not aware of side effects and dangers associated with her off-label use of amiodarone, including serious lung-related side effects that could lead to her death. Newton would not have taken amiodarone if she had received the medication guide.

In 2013, Newton began to experience many of the symptoms outlined in the medication guide, including shortness of breath, wheezing, trouble breathing, coughing, tiredness, and weakness. Her condition continued to deteriorate, and she experienced increasing pulmonary issues including shortening of breath, deep cough, and difficulty doing things she enjoyed at home. Newton died at Carolina East Medical Center on December 27, 2013, at age 82. Plaintiff is the administrator/executor of Newton's estate.

COURT'S DISCUSSION

A. Standard of Review

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the complaint but "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." Republican Party v. Martin, 980 F.2d 943, 952 (4th Cir. 1992). A complaint states a claim if it contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "Asking for plausible grounds . . . does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal [the] evidence" required to prove the claim. Twombly, 550 U.S. at 556. In evaluating the complaint, "[the] court accepts all well-pled facts as true and construes these facts in the light most favorable to the plaintiff," but does not consider "legal

conclusions, elements of a cause of action, . . . bare assertions devoid of further factual enhancement[,] . . . unwarranted inferences, unreasonable conclusions, or arguments." Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 255 (4th Cir. 2009).

B. Analysis

1. Preemption

The generic defendants seek dismissal of plaintiff's claims against them primarily on the basis of preemption. As pertinent to the court's preemption analysis, plaintiff asserts wrongful death claims premised upon three theories of liability: (a) failure to warn adequately of dangers associated with amiodarone; (b) off-label promotion of amiodarone; and (c) failure to provide a medication guide to distributors. The court will address each theory in turn below.

a. Failure to Warn

Plaintiff includes multiple allegations in the complaint regarding defendants' alleged failure to warn properly of dangers associated with amiodarone. For example, plaintiff alleges:

> [Promotional] campaigns were aggressive and in many situations, focused on the use of the drug for atrial fibrillation and failed to warn prescribing physicians of the potential dangers associated with amiodarone toxicity and dangers to atrial fibrillation patients. (Compl. ¶34) (emphasis added).
>
> Defendants failed to disclose to the FDA, healthcare professionals, consumers, or [Newton], of the information they possessed concerning the incidents and actual adverse medical events, injuries, and deaths suffered by Cordarone®/amiodarone users. (Compl. ¶82) (emphasis added).
>
> [T]he Cordarone®/amiodarone, manufactured and/or supplied by Defendants 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. (Compl. ¶88) (emphasis added).
>
> [T]he warnings for Cordarone®/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 [Newton] of the actual risks associated with this drug. (Compl. ¶ 99) (emphasis added).

These claims against the generic defendants premised upon failure to provide adequate warnings accompanying the sale and distribution of amiodarone, however, are preempted by federal law. In particular, because the Food Drug Cosmetic Act (FDCA) and related regulations limit a generic manufacturer's ability to attach additional warnings to their drug, such failure-to-warn claims against the generic defendants are preempted. See PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011) (citing 21 CFR § 314.150(b)(10)); Drager v. PLIVA USA, Inc., 741 F.3d 470, 479 (4th Cir. 2014) (holding claims preempted where based on allegations "that, through its promotional and warning materials, [generic defendant] made negligent misrepresentations and fraudulently concealed information about the safety of its product from consumers and medical professionals").

In response to the generic defendants' motions to dismiss, plaintiff does not seek to advance her failure-to-warn claims. Rather, she argues that liability in this case is based instead upon defendants' promotion of amiodarone for off-label uses and defendants' failure to provide a medication guide. The court will address these theories of liability below. For present purposes, it suffices that plaintiff's failure-to-warn claims must be dismissed with prejudice on the basis of preemption.

b. Off-label promotion

Plaintiff asserts that defendants' off-label promotion of Cordarone®/amiodarone was in violation of the FDCA and related regulations, thus providing a basis for liability under a state law theory of negligence per se. This claim is preempted, although in a different manner than the failure-to-warn claims.

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. In this manner, 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.").

Thus, based on 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 F. App'x 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, plaintiff's claim of negligence per se based upon a violation of the FDCA is impliedly preempted under Buckman. Plaintiff asserts that defendants' off-label promotion of Cordarone®/amiodarone violated FDCA provisions making it "unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug." (Compl. ¶34 (citing 21 U.S.C. §§ 331(d), 352(f), and 355)). In particular, plaintiff asserts that, under the FDCA:

> A pharmaceutical company is permitted to disseminate certain information about off-label uses, but such dissemination must adhere to strict requirements. For instance, the manufacturer must submit an application to the FDA seeking approval of the drug for off-label use; the manufacturer must provide its marketing materials to the FDA prior to dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, 'additional objective and scientifically sound information . . . necessary to provide objectivity and balance.' . . . . This law also requires pharmaceutical companies to furnish federal regulators with advance copies of the information they disseminate.

(Id. citing 21 U.S.C. § 360aaa, et seq.).

Plaintiff does not identify any North Carolina law paralleling and predating these FDCA requirements regarding off-label promotion of drugs approved for public consumption. Because North Carolina law does not contain such restrictions and guidelines regarding off-label promotion of drugs with labels approved by the FDA, plaintiffs claims based upon such off-label promotion are impliedly preempted under Buckman. The restrictions and guidelines placed upon pharmaceutical companies for off-label promotion are entirely dependent upon the statutory and regulatory scheme created by the FDCA, which balances recognized benefits of off-label use with

potential harms associated with promotion of such use. See Buckman, 531 U.S. at 351 ("[O]ff-label use is generally accepted"); 351 n. 5 ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize."); cf. Talley v. Danek Medical, Inc., 179 F.3d 154, 161 (4th Cir. 1999) (stating that "[t]he administrative requirement that a given device be approved by the FDA before being marketed – as opposed to a specific substantive requirement that a device be safe and effective – is only a tool to facilitate administration of the underlying regulatory scheme," and not a sufficient basis for a negligence per se claim). Thus, because plaintiff's claim exists solely by virtue of the FDCA regulations regarding off-label promotion, and because such regulations do not have a parallel in North Carolina law, plaintiff's claims based upon off-label promotion are preempted.

This holding is consistent with prior decisions by this court and others rejecting state law claims similarly premised upon off-label promotion in violation of the FDCA. See, e.g, Williams v. Zimmer US Inc., No. 5:14-CV-468-F, 2015 WL 4256249, at *7 (E.D.N.C. July 14, 2015) (holding preempted "claims of off-label use and promotion of a medical device, allegedly in violation of the FDCA"); Evans, 2014 WL 2535221, at *2 ("At bottom, plaintiff seeks to hold Anulex liable for off-label promotion of its X-close suture device, but such claim is impliedly preempted as it exists solely by virtue of the requirements of the FDCA."); Wright v. Medtronic, Inc., 81 F. Supp. 3d 600, 612 (W.D. Mich. 2015) (holding that a "[l]ack of a traditional state-law duty to refrain from off-label promotion" requires preemption of state law claim under Buckman).

Plaintiff suggests, nonetheless, that her claim survives preemption because negligence per se is a traditional state tort law principle permitting recovery based upon the violation of any health and safety statute. Buckman requires more, however, than the existence of a general state law

principle providing a cause of action for violation of a health and safety statute. Buckman requires pre-existing "state-law causes of actions that parallel federal safety requirements." 531 U.S. at 353. The claim must be "premised on conduct that . . . would give rise to a recovery under state law even in the absence of the FDCA." Williams, 123 F. Supp. 3d at 746. Here, plaintiff has not alleged conduct by the generic defendants that would give rise to recovery for off-label promotion under North Carolina law in the absence of the FDCA.

In sum, plaintiff's claims based upon off-label promotion are preempted under Buckman and must be dismissed as a matter of law.

c. Medication Guide

Plaintiff's claims based upon the failure to provide a medication guide are preempted under Buckman in the same manner as her off-label promotion claims. The requirement to provide a medication guide is grounded solely in the FDCA and related regulations, as noted in the complaint:

> [The generic defendants] were required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand formulation manufacturer . . . and as updated as directed by the FDA. (Compl. ¶ 36 (citing 21 U.S.C. §355(j)(2)(A)(v) & 355(j)(4)(G))) (emphasis added).
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> [The generic defendants] were responsible by federal regulation for ensuring that the appropriate warning labels and Medication Guides were provided to [Newton]. (Compl. ¶41).
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> [Newton's] distributor and pharmacist were not provided a Medication Guide to give directly to her outside of [her] doctor's office and interaction as required by FDA regulations by the [generic defendants]. (Compl. ¶44).
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> Each manufacturer who ships a container of an FDA approved drug product for which a Medication Guide is responsible for ensuring that Medication Guides are available for distribution to patients. (Compl. ¶45 (citing 21 C.F.R. § 208.24)).
>
> The failure to provide each patient a 'Medication Guide' by failing to provide the Medication Guides to the distributor for ultimate distribution to the patient with the

> drug is a direct violation of the FDA's mandate to the manufacturers of the drug intended to warn patients directly outside the communication with the prescribing physician, of the very dangers of amiodarone toxicity that killed [Newton]. (Compl. ¶119) (emphasis added).

Because the requirement to provide a medication guide to distributors is based solely in the requirements of the FDCA and related regulations, which requirements did not exist previously under North Carolina common law, plaintiff's claims based upon failure to provide a medication guide are preempted under Buckman. See 531 U.S. at 352.

In sum, plaintiff's claims against the generic defendants must be dismissed as a matter of law on the basis of preemption.

2. Defendant Wyeth

Defendant Wyeth moves to dismiss all claims against it on the basis that Newton is not alleged to have used defendant Wyeth's brand-name Cordarone®, but instead used only generic amiodarone manufactured and sold by the generic defendants. Under North Carolina law, a defendant may not be held liable for injuries allegedly caused by the use of another's product. See, e.g., Elledge v. Pepsi Cola Bottling Co. of Winston-Salem, 252 N.C. 337, 338 (1960); Kientz v. Carlton, 245 N.C. 236, 240, 96 S.E.2d 14, 17 (1957) ("[T]he duty owed by each defendant to plaintiff is determined by the relationship subsisting between them.").

On this basis, this court and others have dismissed claims brought by plaintiffs against brand-name drug manufacturers where plaintiffs have only ingested generic drugs. See, e.g., Stoddard v. Wyeth, Inc., 630 F. Supp. 2d 631, 634 (E.D.N.C. 2009) ("[A] manufacturer of a brand name pharmaceutical may not be held liable for injuries stemming from the use of another manufacturer's generic bioequivalent."); In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig., 756 F.3d 917, 936 (6th Cir. 2014) (affirming "settled law that the plaintiff must assert that the defendant's

product caused the plaintiff's injury"). Plaintiff does not allege any factual basis to hold otherwise here. Accordingly, plaintiff's claims against defendant Wyeth must be dismissed without prejudice.

CONCLUSION

Based on the foregoing, defendants' motions to dismiss (DE 23, 34, 41) are GRANTED. Plaintiff's claims against defendants Teva, Barr, and Zydus, are DISMISSED WITH PREJUDICE. Plaintiff's claims against defendant Wyeth are DISMISSED WITHOUT PREJUDICE.

SO ORDERED, this the 20th day of July, 2016.

LOUISE W. FLANAGAN
United States District Judge