UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
FRANKFORT

CATHY MOORE, Plaintiff, v. ZYDUS PHARMACEUTICALS (USA), INC., Defendant.	)	Civil No. 3:16-cv-00017-GFVT **MEMORANDUM OPINION & ORDER**

*** *** *** ***

Cathy Moore seeks to recover for alleged harm caused by her use of a generic drug. As explained below, in large measure Moore has no avenue of recovery. This is a function of federal preemption. Hence, the Defendant Zydus Pharmaceuticals' Motion to Dismiss [**R. 30**] is **GRANTED in PART and DENIED in PART**.

I

Plaintiff Cathy Moore suffered from a medical condition known as atrial fibrillation, for which she was prescribed a 90-day course of 200 milligram amiodarone hydrochloride tablets. [R. 1 at 8.] Amiodarone hydrochloride is a prescription medication created by Wyeth-Ayerst under the brand name Cordarone and distributed as a generic drug by Zydus under the label Amiodarone. [*Id.* at 6-8.] According to the Federal Drug Administration, amiodarone hydrochloride should be prescribed "for the treatment of only the following documented, life-threatening, recurrent ventricular arrhythmias when these arrhythmias have not responded to other antiarrhythmic agents or when alternative agents have not been tolerated: Recurrent

ventricular fibrillation; Recurrent hemodynamically unstable ventricular tachycardia" because there are "potentially life-threatening side-effects." Fed. Drug Admin., Information for Healthcare Professionals: Amiodarone (marketed as Cordarone) (2013).[1] Those side-effects include "potentially fatal toxicities, including pulmonary toxicity, hepatic injury, and worsened arrhythmia" as well as nerve injuries and vision problems, amongst many others.[2] *Id.*; [R. 1 at ¶33, R. 1 at 11-18.] The FDA requires that any manufacturer or distributer of amiodarone hydrochloride must provide approved labels, warnings, and medication guides to those prescribed the medication. [R. 1 at ¶27.]

Cathy Moore alleges that in November of 2014, she began to experience symptoms of vision impairment following her Amiodarone prescribed treatment. [R. at ¶38.] By September of 2012, Ms. Moore's vision troubles had escalated into blindness, with subsequent medical evaluations finding that the cause of her symptoms was amiodarone toxicity. [*Id.*] She believes that Wyeth-Ayerst and Zydus, despite knowing of the inherent dangers posed to patients, engaged in an advertising campaign aimed at physicians that was designed to promote the use of Amiodarone for "off-label" treatments or treatments of diseases that were not of a "last resort" in nature. [R. 1 at 4-8.] Moore alleges that "[c]orrection of atrial fibrillation was never an FDA approved use of Cordarone or Amiodarone," thus, she believes that the "off-label" prescription of that drug is the cause of her symptoms. [*Id.* 8-9.] Moore further alleges that, at the time of her medical treatment, she had not yet received the required medication guide for her prescribed Amiodarone. [*Id.* at 9.] Had she received this medication guide, Ms. Moore claims she would have been more aware of the "off-label" use and the dangerous side-effects associated with the

[1] <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm084108.htm>

[2] For a full list of side-effects, *see* ZyGenerics Medication Guide Amiodarone Hydrochloride Tables. <http://www.zydususa.com/wp-content/plugins/products/MedicationGuide/Amiodarone%20HCl%20Tablets.pdf>

ingestion of Amiodarone. [*Id.* at 9-10.]

Moore filed the present diversity action against both Wyeth and Zydus on February 29, 2016. [R. 1.] None of the parties contest the Court's jurisdiction. The complaint contains seven causes of action directed at Zydus: (1) negligence; (2) gross negligence; (3) strict products liability – failure to warn; (4) negligent failure to warn; (5) breach of implied warranty; (6) breach of express warranty; and (7) fraud and deceit (in part, for off-label marketing). In May of 2016, Moore voluntarily dismissed Wyeth-Ayerst, leaving Zydus as the sole defendant. [R. 17.] Zydus filed a Motion to Dismiss [R. 30] and argues that Moore's claims are pre-empted by federal law, or, in the alternative, that her claims are insufficiently pled to satisfy the requirements of a complaint under Federal Rules of Civil Procedure 8 and 9. [R. 30-1.]

II

Federal Rule of Civil Procedure 12(b)(6) allows a defendant to seek dismissal of a complaint which fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). In making such a motion, "[t]he defendant has the burden of showing that the plaintiff has failed to state a claim for relief." *DirecTV, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007) (citing *Carver v. Bunch*, 946 F.2d 451, 454-55 (6th Cir. 1991)). Federal Rule of Civil Procedure 8 requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, to survive a motion to dismiss, the complaint "must contain either direct or inferential allegations" establishing each material element required for recovery under some actionable legal theory. *Bishop v. Lucent Technologies, Inc.*, 520 F.3d 516, 519 (6th Cir. 2008) (internal citation and quotation marks omitted).

When reviewing a Rule 12(b)(6) motion, the Court "construe[s] the complaint in the light most favorable to the plaintiff, accept[s] its allegations as true, and draw[s] all reasonable

inferences in favor of the plaintiff." *DirecTV, Inc.*, 487 F.3d at 476 (citation omitted). The Court, however, "need not accept as true legal conclusions or unwarranted factual inferences." *Id.* (citation omitted). Moreover, as is now well known, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In other words, the facts that are pled must rise to the level of plausibility, not just possibility – "facts that are merely consistent with a defendant's liability . . . stop[ ] short of the line between possibility and plausibility." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557). According to the Sixth Circuit, "[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." *DirecTV, Inc.*, 487 F.3d at 476 (citing *Twombly*, 550 U.S. at 556). Thus, the plaintiff must at least "provide the grounds of his entitlement to relief, [which] requires more than labels and conclusions. . . ." *Twombly*, 550 U.S. at 555 (internal citations and quotation marks omitted).

When ruling on a Rule 12(b)(6) motion, a district court generally may not consider matters presented outside the pleadings unless it converts the motion into one for summary judgment under Rule 56. Fed. R. Civ. P. 12(d); *Heinrich v. Waiting Angels Adoption Servs., Inc*., 668 F.3d 393, 405 (6th Cir. 2012). The district court, however, also has the discretion to ignore such evidence and resolve the motion solely on the basis of the pleadings. *Heinrich*, 668 F.3d at 405; *Max Arnold & Sons, LLC v. W.L. Hailey & Co., Inc*., 452 F.3d 494, 502-03 (6th Cir. 2006) (collecting cases). Certain matters beyond the allegations in the complaint such as "matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint, also may be taken into account." *Amini v. Oberlin College*, 259 F.3d 493, 502

(6th Cir. 2001) (citations and internal quotation marks omitted). Additionally, the Sixth Circuit has held that when a *defendant* attaches undisputed documents to a motion to dismiss, they "are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim." *Id.* (citations and internal quotation marks omitted). In the instant action, all documents considered by the court were either matters of public record, orders, or items appearing in the record of the case, therefore the court will not convert the motion into one for summary judgment.

A

Zydus argues that "[Moore's] causes of action based on the adequacy of the product warnings under state law is preempted by federal law," based upon their reading of the decision in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). [R. 30-1 at 1-2.] Zydus further argues that Moore is not afforded a private right of action by the Food, Drug, and Cosmetics Act (FDCA) or Food and Drug Administration (FDA) regulations, citing to the decision in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2011). [*Id.*] To understand the arguments presented by Zydus, a brief explanation of the framework established by the FDCA and FDA regulations will be helpful.

Under the FDCA, the FDA provides approval and makes regulations regarding the manufacture and prescription of drugs by brand name and generic producers. *See* 21 C.F.R. § 314.50(c)(2)(i); 21 C.F.R. § 314.94(a)(8). Drug companies that bring a new product to market are required to file a New Drug Application ("NDA") with the Food and Drug Administration to market their drug. *See* 21 U.S.C. § 355(j)(2)(A). New Drug Applications require costly and time intensive clinical trials. In contrast, generic drugs receive accelerated approval by the FDA through the submission of an Abbreviated New Drug Application ("ANDA") that only requires

the generic manufacturers to provide proof that their product is identical in both composition and labelling to a previously approved brand name drug and to maintain the labelling pursuant to the requirements imposed on the brand name drug by the FDA. 21 U.S.C. § 355(j)(2)(A); 21 U.S.C. § 355(j)(4)(G). Labeling includes "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). This labeling must be "the same as the labeling approved for the [brand-name] drug." 21 U.S.C. § 355 (j)(2)(A)(v).

Drugs that have been approved through the NDA process are able to unilaterally strengthen drug warnings without prior approval by the FDA. *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2575 (2011). But, ANDA drugs cannot disseminate additional information, update warnings, or directly correspond with healthcare providers concerning enhanced warnings as "[f]ederal law . . . demand[s] that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id.* at 2578. Amiodarone is a generic drug, thus Zydus has a "duty of sameness" and must use identical ingredients and labelling (including warnings) utilized by the brand name drug that is emulated. *Mensing*, 131 S.Ct. at 2574. In the *Mensing* decision, the Supreme Court ruled that the plaintiff's state law claims based on liability under failure to warn were pre-empted by federal law when dealing with a generic brand drug manufacturer as the generic drug manufacturer could not change its labelling without violating FDA regulations. *Id.* at 2575. Preemption, or impossibility preemption, arises when there is a conflict between state and federal law and "it is impossible for a private party to comply with both state and federal requirements." *Mensing*, 131 S.Ct. at 2570. The decision in *Mensing* was applied by the Sixth Circuit case *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig*., 756 F.3d 917, 925 (6th Cir. 2014).

In addition to federal pre-emption, Zydus argues that Moore is not provided a private right of action to bring claims on the basis that Zydus allegedly failed in a duty that is solely established and enforced by the FDCA. [R. 30-1 at 13.] The FDCA does not specifically provide a legal avenue for a private party to enforce the provisions; instead, it calls for "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). The Supreme Court has interpreted this clause of the statute and found that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance…" *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, at 349 n.4 (2011).

Despite the applicability of impossibility preemption in many similar actions, Moore argues that the instant action is not pre-empted by federal law and that the *Mensing* and *Bartlett* analysis is distinguishable. [R. 32 at 4.] Namely, Moore believes that the generic manufacturer was capable of "discharg[ing] its obligations under applicable state common law without violating federal law" therefore, impossibility "preemption is inapplicable." [R. 32 at 4.] Zydus disagrees and argues that the claims brought for failure to warn, design defect, and manufacturing defect should be dismissed as those claims are preempted by federal law. [R. 30 at 8.]

B

PLIVA, Inc. v. Mensing, 131 S.Ct. 2567 (2011) clarified that "[f]ederal law impliedly pre-empts state law when state and federal law "conflict"—i.e., when "it is impossible for a private party to comply with both state and federal law." *Id.* at 2587. "[A]fter *Mensing* and *Bartlett*, Plaintiffs cannot sue a generic manufacturer on a failure to warn claim or a state law design defect claim that turns on the adequacy of a drug's warnings." *In re Darvocet, Darvon, &*

Propoxyphene Prod. Liab. Litig., 756 F.3d 917, 925 (6th Cir. 2014). This conclusion was reached, in part, due to the generic manufacturer's "duty of sameness" which does not allow for the generic manufacturer to modify the warnings or information provided to consumers.

In *Mensing*, plaintiffs consumed a generic form of metoclopramide and alleged a number of state law claims, but, the Supreme Court determined that state-law tort claims brought against manufacturers of generic drugs are preempted by federal law. *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2572 (2011). In addition to preemption of state law tort claims premised on failure-to-warn, the Supreme Court found that, due to the federal statutory scheme, generic manufacturers were not allowed to send letters ("Dear Doctor" letters) to providers concerning the risks associated with the drug or deviate from the FDA approved labeling. *Id.* at 2576-2581. The Court extended this holding in *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

In *Bartlett*, the Court "h[e]ld that state-law design-defect claims that turn on the adequacy of a drug's warnings are preempted by federal law under *PLIVA*." *Id.* at 2470. The *Bartlett* Court explained that where "it was impossible for [the generic drug manufacturer] to comply with both its state-law duty to strengthen the warnings on [the drug]'s label and its federal-law duty not to alter [the drug]'s label . . . the state law is preempted." *Id.* at 2473. "Thus, after Mensing and Bartlett, Plaintiffs cannot sue a generic manufacturer on a failure to warn claim or a state law design defect claim that turns on the adequacy of a drug's warnings." *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 925 (6th Cir. 2014).

Nonetheless, Moore argues that the reasoning in *Mensing* and *Bartlett's* is inapplicable because "it would not violate federal law for Zydus to have provided a Medication Guide in conjunction with the prescription." [R. 32 at 7.] Moore argues that the Medication Guide would have made clear that her use of the drug was "off-use" and that "Zydus failed to comply with

federal law when it took no steps to ensure that the Medication Guide made it to her or to other consumers." [R. 32 at 11.] More specifically, "the allegation is not one of an adequacy or 'content' failure to warn . . . but an actual and physical negligent failure of Zydus to fulfill its federally-mandated responsibility to ensure that Medication Guides are available for distribution directly to patients with each prescription. [R. 32 at 11.] These accusations, in combination with Moore's resulting blindness, and over thirty pages of additional materials, support Moore's causes of action that allege negligence and gross negligence on behalf of both Defendants Wyeth-Ayerst Laboratories and Zydus Pharmaceuticals. [R. 1 at 30.]

Ultimately, the claim against Zydus for failure to provide a medication guide is barred by 21 U.S.C. § 337(a). The FDA requires drug manufacturers to issue medication guides to accompany some prescription medications when the agency determines that certain circumstances are met:

> (1) The drug product is one for which patient labeling could help prevent serious adverse effects. (2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product. (3) The drug product is important to health and patient adherence to directions for use is crucial to drug's effectiveness.

21 C.F.R. § 208.1. In December 2004, the FDA determined that Cordarone must be accompanied by a medication guide. Producers of generic bioequivalent drugs, such as Zydus, have a duty of "sameness," therefore Zydus must distribute the same medication guide. [R. 1 at ¶28; R. 30-1 at 7.]

Zydus, the manufacturer of such drugs, must either provide "Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product" or provide "the means to produce Medication Guides in sufficient numbers to

distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product." 21 C.F.R. § 208.24. But, at the time a prescription drug is dispensed, it is the pharmacy (or authorized dispenser) that must "provide a Medication Guide directly to each patient," not the manufacturer of the drug. 21 C.F.R. § 208.24(e).

Ms. Moore's allegations state that she "was not provided the Medication Guide," [R. 1 at 9], and that manufacturers have a "non-delegable" duty to ensure the consumer receives a medication guide. [R. 1 at 11.] Importantly, in one numbered paragraph, Moore also asserted that, "[a]ccording to the Pharmacies, no manufacturer is providing them or the patient's [sic] medication guides." [R. 1 ¶ 115.] While this would be a violation of the manufacturer's legal duty, Zydus' obligation to provide a medication guide arises solely from responsibility imposed by the FDCA. *See* 21 C.F.R. § 208.24. Taken as true, Zydus may not have physically given Medication Guides to the authorized dispensers but the complaint fails to address whether Zydus provided pharmacies with "the means to produce Medication Guides" and Moore's briefing neglected to contemplate whether the online Medication Guide and resources, discussed *supra* section "I," satisfy Zydus's lawful obligation. 21 C.F.R. § 208.24(c).

Even so, the Supreme Court made clear that it must be the Federal Government, not private litigants, that bring suit for violation of the FDCA. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, at 349 n.4 (2011) (stating that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance…"); *see also Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586 (6th Cir. 2013) (finding "[w]here the claim is based on traditional state-tort-law principles, the lack of a private cause of action within a federal regulatory scheme will not preempt the claim for damages (even if state

regulations might be preempted)" but that "if the claims 'exist solely by virtue of' the regulatory scheme, they are preempted."). Since Ms. Moore's claim concerning receipt of the medication guide exists exclusively due to the federal regulatory scheme, her claim must fail as the cause of action is merely based upon alleged violation of the FDCA and it is the FDA, not Ms. Moore, that "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration."[3] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

Further, concerning receipt of the medication guide by Moore, Kentucky has adopted the Restatement (Third) of Torts: Products liability § 6(d), or "learned intermediary doctrine." The learned intermediary doctrine establishes an exception to the manufacturer's duty to warn and allows for that duty to be satisfied "if adequate warning [is] given to [the] patient's health care provider." *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004). The briefing did not extensively discuss this doctrine and Moore failed to respond to Zydus's argument that this exception would apply if the Court determined that the duty was not preempted. But, since the Court's ruling in favor of Zydus concerning provision of the Medication Guide rests on preemption, the merits of Zydus's argument concerning the learned intermediary doctrine need not be addressed.

C

Besides distribution of a Medication Guide, Moore asserts negligence and gross negligence against Zydus. [R. 1 at 30.] In Kentucky, to establish negligence, a plaintiff must demonstrate the existence of a duty, breach thereof, and consequent injury, which includes

[3] Moore's complaint even recognizes that this claim is based upon FDA regulations. In the paragraph concerning the cause of action accruing due to gross negligence the complaint states: "[d]espite the FDA requirements that the drug companies provide the patients medication guide with FDA written material with their Amiodarone prescription, no medication guide was provided to Cathy Moore…" [R. 1 at ¶ 113.]

"actual injury or harm to the plaintiff and legal causation between the defendant's breach and the plaintiff's injury." *Pathways, Inc. v. Hammons*, 113 S.W.3d 85, 88 (Ky. 2003); *Mullins v. Commonwealth Life Insurance Company*, 839 S.W.2d 245, 247 (Ky.1992). Establishing gross negligence requires "something more than the failure to exercise slight care." *City of Middlesboro v. Brown*, 63 S.W.3d 179, 181 (Ky. 2001) (quoting *Cooper v. Barth, Ky.*, 464 S.W.2d 233, 234 (Ky. 1971)). In fact, "there must be an element either of malice or willfulness." *Id.* More recently, the Kentucky Supreme Court has defined "gross negligence," in the context of punitive damages, as requiring a "finding of failure to exercise reasonable care, and then an additional finding that this negligence was accompanied by wanton or reckless disregard for the lives, safety or property of others." *City of Middlesboro*, 63 S.W.3d at 181 (citing *Horton v. Union Light, Heat & Power Co.*, 690 S.W.2d 382, 389-90 (Ky. 1985)).

Examining the complaint in its entirety, to the best of the Court's understanding, Moore alleges that Zydus was negligent in the following ways: "[Zydus] . . . [sought to] increase Amiodarone sales as an initial, first-line anti-arrhythmic medication, for which Amiodarone has never received FDA approval, i.e., an "off-label" use". [R. 1, ¶14.] "[Zydus made a decision to] actively conceal the illegal means that would be used to market the drug." [R. 1, ¶17.] "Cathy Moore was not provided the Medication Guide or the appropriate and up to date warning labels that were required to be given to Cathy Moore…" [R. 1, ¶32.] "[Distribution of the Medication Guide is a] "non-delegable" duty, and one that cannot be accomplished by other means." [R. 1, ¶37.] "[Zydus] . . . had actual or constructive knowledge that [] Amiodarone cause[s] and contribute[s] to severe and disabling medical conditions and death, such as those experienced by Cathy Moore…" [R. 1, ¶65.] "[Zydus was] on notice of numerous instances of catastrophic injuries caused by ingestion of Cordarone®/Amiodarone. [R. 1, ¶70; *see also*, R.1, ¶71.]

Further, Moore's complaint stated that: "Zydus . . . actively promoted their generic Amiodarone in the stream of commerce for the "off-label" uses openly promoted by Defendant Wyeth." [R. 1, ¶73.] "[D]espite FDA warnings and thousands of adverse patient experiences, [Zydus] continued their fraudulent marketing, promotional, and sales practices from 1999 through the present date." [R. 1, ¶75.] "[Zydus] . . . concealed information about catastrophic injuries and death, and thousands of serious adverse medical events." [R. 1, ¶76.] "Amiodarone manufactured and/or supplied by [Zydus] was and is unaccompanied by proper warnings" [R. 1, ¶77.] "[Zydus] failed to warn of material facts regarding the safety and efficacy of Cordarone®/Amiodarone." [R. 1, ¶78.] "Amiodarone manufactured, distributed, and/or supplied by [Zydus] was defective due to inadequate post-marketing warning and instruction…" [R. 1, ¶81.] "[Zydus] . . . concealed this adverse event information, [and] simultaneously engaged in a massive and fraudulent marketing and promotional scheme." [R. 1, ¶82.] "[Zydus] . . . also promoted Cordarone®/Amiodarone for heart conditions less severe than life-threatening ventricular arrhythmia." [R. 1, ¶83.] "[T]he warnings for []Amiodarone in effect during the relevant time period were vague, incomplete, and/or otherwise wholly inadequate…" [R. 1, ¶88.] "The injury of Cathy Moore was directly and proximately caused by the negligent actions of the [Zydus]…" [R. 1, ¶109.] "Despite the FDA requirements that the drug companies provide the patients medication . . . no medication guide was provided to Cathy Moore. [R. 1, ¶113.] Finally, "[Zydus is] guilty of gross negligence for failure to provide the FDA required medication guide." [R. 1, ¶116.]

Moore included allegations, as discussed *supra* section "B", that neither she nor pharmacies received a medication guide. [*Id.* at ¶115-16.] Many of the remaining allegations either accuse Wyeth of rampant misconduct or Zydus of failure to properly warn of

Amiodarone's various side effects, but any cause of action brought against Zydus for negligence grounded in failure to warn is preempted by federal law. *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2575 (2011); [*See* R. 1, ¶¶32, 77, 78, 81, 88.]

It is difficult to determine which Defendant is accused of illicit behavior, as the Complaint combines discussion of misconduct by "Defendants" rather than addressing the singular conduct of Zydus or Wyeth. But, Moore supports her state law negligence claim by drawing the Court's attention to the allegation that Zydus improperly promoted off-label use of amiodarone for atrial fibrillation and "the more general failure to provide any warning associated within the placement of a hazardous product into commerce." [R. 32 at 4.] Moore argues that both Kentucky common law and the Kentucky Product Liability Act, Ky. Rev. Stat. 411.300 *et seq.*, provide viable state law claims. *Id.*

In response, Zydus argues that Moore's negligence claims are solely premised on violation of federal law and the standards established by the FDCA. [R. 30-1 at 16-17.] [R. 32 at 4 (citing Ky. Rev. Stat. 411.300 *et* seq.] Zydus cites to a fellow district court in the Western District of Kentucky. [R. 30-1 at 16.] In discussing negligence per se, the District Court determined that Kentucky law mandated that negligence per se claims be brought under KRS § 446.070, "which codified the common law negligence per se tort" and that "[t]he Kentucky Supreme Court determined that the General Assembly did not intend KRS § 446.070 'to embrace the whole of federal laws and the laws of other states and thereby confer a private civil remedy for such a vast array of violations." *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 681 (W.D. Ky. 2013) (citing *T & M Jewelry, Inc. v. Hicks ex rel. Hicks*, 189 S.W.3d 526, 530 (Ky.2006) (finding that "any statute in KRS 446.070 has been held to be limited to Kentucky statutes and not to federal statutes or local ordinances."). The district court concluded, and this

Court agrees, "violations of federal law do not support negligence per se claims under Kentucky law." *Sadler*, 929 F. Supp. 2d at 681 (citing *St. Luke Hosp. Inc., v. Straub*, 354 S.W.3d 529, 534 (Ky. 2011) (holding that "[v]iolations of federal laws and regulations and the laws of other states do not create cause of action based on KRS 446.070."); *Cf. Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 588 (6th Cir. 2013) (recognizing that "courts have found that, **as long as authorized by state law**, negligence per se suits premised on violation of federal law could go forward") (emphasis added)).

The Kentucky Supreme Court's holding in *T & M Jewelry, Inc. v. Hicks ex rel. Hicks*, 189 S.W.3d 526, 530 (Ky.2006) offers binding and unequivocal precedent concerning the scope of KRS 446.070 and demonstrates that Moore does not have a state based right to sue for negligence in this matter. Other authority also requires dismissal, pursuant to Federal Rule of Civil Procedure 12(b)(6), of the first and second cause of action for negligence and gross negligence. Ms. Moore alleges that she was harmed by Zydus's "manufacture, marketing, distribution[,] and sale of" Amiodarone. [R. 1 at 30.] But, importantly, the "duty of sameness" prevents Zydus, the generic producer of Amiodarone, from altering any warnings, labeling, or the composition of the generic drug from that of the listed drug. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013) (stating that "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based").

Moore cites to a number of unpublished district court cases to suggest that Moore's various causes of action are not preempted and that she has presented a claim for relief that satisfies the burdens imposed by the federal pleading standard. Most of the cases are merely persuasive authority and distinguishable. For instance, to support Moore's claim for negligence

per se for failure to provide the Medication Guide, Moore cites to *Marvin v. Zydus Pharmaceuticals, Inc.*, WDWI-15-cv-748-bbc, a case from the Western District of Wisconsin. [R. 32 at 16-17.] The district court determined that § 337(a) did not prohibit the plaintiff from bringing a claim for negligence per se (for failing to provide a medication guide) because the claim was not preempted under *Buckman* and the allegation "meets the requirements for negligence per se claims under Wisconsin law." [R. 32-8 at 4-5.] In Kentucky this matter is distinguishable. Under Kentucky law and the Kentucky Supreme Court's analysis of KRS 446.070, which codifies the doctrine of negligence per se, the Court found that the statute "did not intend for KRS 446.070 to . .. confer a private civil remedy for" violations of federal law. *T & M Jewelry, Inc. v. Hicks ex rel. Hicks,* 189 S.W.3d 526, 530 (Ky.2006).

Significantly, Moore has not alleged that the generic drug was defectively manufactured or that Zydus failed to adhere to the formula that was previously approved by the FDA. Rather, the complaint primarily addresses the effectiveness of warnings, various side-effects, and Moore's use of the generic drug itself. Accordingly, Moore fails to "state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facts that are pled failed to rise to the level of plausibility, as Moore's claims are preempted and cannot succeed as a matter of law. *See, e.g., Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378, 391 (6th Cir. 2013) (recognizing that the Courts of Appeals "have interpreted *Mensing* to broadly preempt claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturers"); *Bell v. Pfizer*, 716 F.3d 1087 (8th Cir. 2013) (remanding a case for further consideration of design-defect and breach of implied warranty but determining that the "vast majority" of Plaintiff's allegations were "preempted failure to warn claims"); *Gaeta v. Perrigo Pharm. Co.*,

469 Fed. Appx. 556 (9th Cir. 2012), *aff'g* 562 F.Supp.2d 1091 (N.D. Cal. 2008). Moore's allegations of negligence and gross negligence are mere "labels and conclusions" and do not provide the grounds for Ms. Moore's entitlement to relief on these claims. *Twombly*, 550 U.S. at 556. For these reasons, the first two counts of Moore's Complaint will be dismissed.

D

Moore also brings claims under strict products liability for failure to warn and negligent failure to warn. [R. 1 at 31-35.] The traditional failure to warn claim under products liability involves a dereliction of duty in which a manufacturer or producer knows, or has reason to know, that their product presents unreasonable risks of injury to a user but fails to warn said users of the inherent dangers. *See* Restatement (Third) of Torts: Proc. Liab. § 2 (1998); 13 Ky. Prac. Tort Law § 13:8 (2016 ed.). Specifically, Moore alleges "[Zydus] knew or should have known of the defective condition, characteristics, and risks associated with" Amiodarone and that "[Zydus] consciously disregarded this increased risk of harm by failing to warn of such risks…" [R. 1 at 32.]

In Moore's Response, she argues that her claims are viable under Kentucky common law "and consistent with Kentucky's Product Liability Act, Ky. Rev. Stat. 411.300 *et seq*." [R. 32 at 4.] However, the Sixth Circuit held in *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011), that following *PLIVA v. Mensing*, 131 S.Ct. 2567 (2011), "federal law preempts state law that imposes on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims." *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011). While "[t]he [Products Liability Act] applies to all damage claims arising from the use of products, regardless of the legal theory advanced," *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky.1997), the Moore's cause of action is, at its core, attacking the adequacy of the warnings

provided by Zydus.

For example, in the complaint's discussion of strict products liability for failure to warn, Moore claims that "[t]he warnings and directions provided with Amiodarone by [Zydus] failed adequately to warn of the potential risks and side effects of Amiodarone and the dangerous propensities of said medication," and "Wyeth, as the brand-name manufacturer, designer and marketer of Amiodarone, owed a duty of care to Moore and other consumers of Amiodarone, to ensure they receive proper warnings." [R. 1 at ¶¶ 122-123.]

Consistent with Supreme Court and Sixth Circuit precedent, Moore's claims for failure to warn pursuant to strict products liability and negligent failure to warn are preempted. *See Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378, 391 (6th Cir. 2013) (recognizing that the Courts of Appeals "have interpreted *Mensing* to broadly preempt claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturers"); *Schrock v. Wyeth Inc.*, 727 F.3d 1273, 1287-90 (10th Cir. 2013).

E

Moore alleges that the Zydus breached both an implied and express warranty, as Zydus impliedly and expressly warranted that the generic medication was safe for its intended use. [R. 1 at 35-36.] More specifically, Moore claims that Zydus "impliedly warranted that Amiodarone . . . was fit for the particular purposes for which it was intended and was sold" and that "[Zydus] breached their written warranties applicable to Amiodarone by continuing their sales and marketing campaigns . . . while they knew of the defects and risks associates with the off label use of such products…" *Id.* The Sixth Circuit case *Strayhorn v. Wyeth Pharmaceuticals* established that claims of breach of implied or express warranty, when dealing with the

inadequacy of labels or warnings included with drugs approved by the FDA and governed by the FDCA, are pre-empted by federal law in these circumstances. *See Strayhorn v. Wyeth Pharmaceuticals*, 737 F.3d 378, 395-96 (6th Cir. 2013).

In *Strayhorn*, the Defendant producer of a generic metoclopramide argued that the Plaintiffs' claims were preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, and the United States Supreme Court decision *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). *Strayhorn*, 737 F.3d at 383-86. The Sixth Circuit Court of Appeals agreed and, in considering claims that arose under Tennessee law, noted that:

> Our conclusion is consistent with this court's previous decision in *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir.2011), cert. denied, —— U.S. ——, 132 S.Ct. 2103, 182 L.Ed.2d 868 (2012), which affirmed the district court's determination that the plaintiffs' state-law claims—centering on a failure to warn under Kentucky law that included claims for breach of implied warranty—were preempted. We further note that Kentucky's implied-warranty regime is substantially the same as that of Tennessee. Compare Ky.Rev.Stat. § 355.2–314 with Tenn.Code Ann. § 47–2–314. To not find preemption in the present case would require us to disregard this court's binding precedent.

Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378, 396 (6th Cir. 2013). As in *Strayhorn*, Ms. Moore's cause of action based upon breach of implied warranty essentially "boil[s] down to the failure to give additional warnings." *Id.* at 395 (holding that "[t]he plaintiffs' implied-warranty claims under Tenn.Code Ann. § 47–2–314 fare no better because they are entirely premised on a failure-to-warn theory"). Consistent with the Sixth Circuit's holding, Ms. Moore's implied-warranty claim fails as preempted and must be dismissed. "In particular, the plaintiff[] do[es] not allege that the generic [Aniodarone she] took was ineffective for treating the [heart condition] for which it was prescribed; only that it was unsafe when used long-term [and off-label] because of the drug's dangerous side effects," but "such implied-warranty claims are preempted by both *Mensing* and *Bartlett*." *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 396 (6th Cir. 2013)

Express warranties are made in Kentucky, pursuant to Kentucky Revised Statute § 355.2-313, by:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.
>
> (2) It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

Ky. Rev. Stat. Ann. § 355.2-313. In the context of reviewing the appropriateness of jury instructions that were provided by a district court, the Sixth Circuit contemplated this Kentucky statute and the process by which an express warranty may be created. *Overstreet v. Norden Labs., Inc.*, 669 F.2d 1286, 1290 (6th Cir. 1982). The Court of Appeals held that "[t]he mere existence of a warranty is insufficient to sustain an action for breach of an express warranty. The warranty must be 'part of the basis of the bargain' between the parties." *Id.* at 1291 (citing Ky. Rev. Stat. Ann. § 355-2313(1) (a), Comment 1(C)).

Ms. Moore bases her express warranty cause of action on statements made "[by] authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, [Ms. Moore], and the general public. [R. 1 at 35-36.] The Complaint does not provide specific examples of any warranties made by Zydus. Presumably, Moore relied upon statements contained in the Medication Guide itself. Yet, seeing that Moore repeatedly states that she did not receive a Medication Guide, the statements contained therein cannot be considered an express warranty by Zydus. Ms. Moore could not contemplate information she had not received as the "basis of the bargain" that was made

between herself and Zydus. *Overstreet*, 669 F.2d at 1291.

Moore's use of Amiodarone for atrial fibrillation was "off-label." [R. 1 at 8-9.] Despite her alleged reliance, the "express-warranty claims are without merit because the labels never explicitly warranted that [Amiodarone] was safe for" the treatment of atrial fibrillation. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 395 (6th Cir. 2013); [R. 30-1 at 13.] Just as in *Strayhorn*, Ms. Moore has not alleged that Zydus warranted that Amiodarone was safe for her off-label use of the drug. Instead, she claims that Zydus expressly warranted that the drug was "safe, effective, fit[,] and proper for its intended use." [R. 1 at 36.] Further, healthcare professionals relied on the express warranties of Zydus in prescribing this medicine to Moore. *Id.* But, Zydus is unable to unilaterally change, modify, alter, or enhance any warnings or warranties provided with the generic drug due to the continual federal "duty of sameness." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013) (stating that "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based").

Moore's express warranty claim is essentially a preempted failure to warn claim that argues the warnings provided by Zydus with Amiodarone were inadequate. Zydus was not at liberty to provide altered warnings or warranties. "When a generic manufacturer cannot obey federal law without being held liable under a state-law warranty action, the state action is preempted." *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 396 (6th Cir. 2013) (citing *PLIVA, Inc. v.* Mensing, 131 S.Ct. 2567, 2577 (2011)). Once again, Moore's causes of action based upon the breach of express and implied warranty will be dismissed for failure to state a claim. Fed. R. Civ. P. 12(b)(6).

F

Now, the Court must turn to the Moore's seventh cause of action for fraud, deceit, and off-label marketing. Moore believes that Zydus engaged in or benefitted from marketing schemes designed to promote off-label uses of Amiodarone and that the Defendants, collectively, engaged in this aggressive campaign to promote the use of Amiodarone for unapproved purposes in order to realize larger profits. [R. 1 at ¶14-20, ¶27, ¶39-64.] Beyond marketing the generic drug, Moore asserts that both Zydus and Wyeth actively deceived medical professionals and patients by concealing material facts concerning the drug's dangerous side effects. In 21 U.S.C. § 331(d), the FDCA prohibits drug manufacturers from either directly or indirectly promoting or marketing their products for uses other than those that have received approval from the FDA. Since Wyeth received FDA approval for specific uses of Cordarone and Zydus cannot deviate in any way in the manufacturing of Amiodarone, it follows that Zydus cannot promote or market their generic brand for off-label purposes.

Zydus makes two arguments in opposition. First, Zydus moves to dismiss the complaint as "[Moore] has failed to cite any Kentucky or Sixth Circuit decisional law that would create a unique Kentucky substantive cause of action grounded in an allegation of off-label promotion..." [R. 36 at 5.] Second, Zydus argues that the complaint has inadequately pled a cause of action pursuant to Federal Rule of Civil Procedure 9(b).

Federal Rule of Civil Procedure 9(b) requires, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9. Courts have read Rule 9(b) to require the complaint to convey "(1) the time, place, and content of the alleged misrepresentation, (2) the fraudulent scheme, (3) the defendants' fraudulent

intent, and (4) the resulting injury." *United States v. Villaspring Health Care Ctr., Inc.*, 2011 WL 6337455 (E.D. KY. Dec. 19, 2011) (citing *Chesbrough v. VPA, P. C.*, 655 F.3d 461, 467 (6th Cir. 2011) (internal quotation marks omitted); *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006) ("[A]t a minimum, Rule 9(b) requires that the plaintiff specify the 'who, what, when, where, and how' of the alleged fraud.") (quoting *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997)). "When deciding a motion to dismiss under Rule 9(b) for failure to plead fraud with particularity, a court must also consider the policy favoring simplicity in pleading, codified in the 'short and plain statement of the claim' requirement of Federal Rule of Civil Procedure 8." *Sanderson v. HCA–The Healthcare Co.*, 447 F.3d 873, 876 (6th Cir.2006). At the same time, "a district court need not accept claims that consist of no more than mere assertions and unsupported or unsupportable conclusions." *Sanderson*, 447 F.3d at 876 (citing *Kottmyer v. Maas*, 436 F.3d 684, 688 (6th Cir.2006)).

The majority of the complaint fails to specify actions undertaken by Zydus and instead conflates accusations of wrongdoing against the two originally named "Defendants." Instead of providing specific details concerning when the wrongful conduct took place, the Complaint alleges that the "Defendants' scheme in the past involved and continues to involve a calculated and deceitful sales campaign…" [R. 1, ¶9.] Some specific accusations were made in the Complaint (for example, R. 1, ¶59 states that Wyeth's "pharmaceutical sales and marketing directors encouraged their respective sales representatives to visit physicians' offices" to promote off-label use), but the complaint unsuccessfully provides a foundation for the "who, what, when, where, and how" of the alleged fraud as to Zydus. *See Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006); [*see also* R. 30-1 at 24 ("[P]laintiff has failed

to identify one specific instance of Zydus' alleged off-label promotion of amiodarone. In contrast, Moore notably provided over half a dozen specific examples of Wyeth's alleged wrongful and fraudulent marketing (Compl. ¶¶ 27, 41, 45, 48, 54, 59, 62)".)]

Moore argues, generally, that state common law provides a cause of action that has not been preempted by federal law. [R. 32 at 4.] Also, Moore brings an alternative argument and requests the Court's leave to amend her pleadings so that she may provide adequate specificity. *Id.* Amendments to pleadings are governed by Federal Rule of Civil Procedure 15, which provides that even if the party does not seek the amendment within the of-right period, the court may give leave to permit such an amendment and should "freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The United States Supreme Court has read this provision broadly and the Sixth Circuit has recognized that "where the underlying facts would support, a motion for leave to amend should be granted, except in cases of undue delay, undue prejudice to the opposing party, bad faith, dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, or futility." *Duggins v. Steak'n Shake*, Inc., 195 F.3d 828 (6th Cir. 1999) (citing *Foman v. Davis*, 371 U.S. 178 (1962)).

At this stage, it is unclear whether providing Moore with an opportunity to amend her complaint would be futile. Adequate specificity concerning fraud, deceit, or off-label marketing as to Zydus may provide Moore with a cognizable right to recovery if her claims are supported by state law and not solely premised on private enforcement of the FDCA. Alternatively, it is also possible new allegations of off-label marketing will make evident that impossibility preemption must again be applied. Accordingly, Moore will be allowed to amend her complaint as to the seventh cause of action. *See* Fed. R. Civ. P. 15(a); *Marks v. Shell Oil Co.*, 830 F.2d 68, 69 (6th Cir. 1987) ("Though the decision to grant leave to amend is committed to the trial court's

discretion, that discretion is limited by Fed.R.Civ.P. 15(a)'s liberal policy of permitting amendments to ensure the determination of claims on their merits.").

III

The Supreme Court has discussed this unique area of law and recognized, from the perspective of many plaintiffs, "finding pre-emption here but not in [other cases] makes little sense." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625 (2011). Were Moore to have continued her suit against the brand-name drug, federal law would not have preempted that lawsuit but the Court "acknowledge[s] the unfortunate hand that federal regulation has dealt" those that are injured by the consumption of generic drugs. This Court, like the Surpreme Court, is not given the "task to decide whether the statutory scheme established by Congress is unusual or even bizarre." *Id.* While true that "different federal statutes and regulations may, as here, lead to different pre-emption results" the laws passed by Congress and enforcement of the Supremacy Clause demand this result. Accordingly, and the Court being otherwise sufficiently advised, it is hereby **ORDERED** as follows:

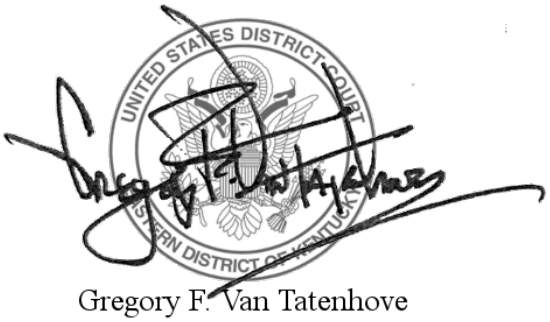
1. Zydus's Motion to Dismiss for failure to state a claim [**R. 30**] is **GRANTED in PART and DENIED in PART**;

2. Zydus's Motion to Dismiss [**R. 30**] is **GRANTED** as to Claims One through Six but **DENIED** as to the Seventh Claim;

3. Moore's Motion for Leave to File an Amended Complaint [**R. 32 at 17**] is **GRANTED**. The Amended Complaint should be limited to the Seventh Claim only; and

4. Moore shall have thirty (30) days from the date of this Order by which to file an Amended Complaint in the record.

This the 29th day of September, 2017.



Gregory F. Van Tatenhove
United States District Judge