IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FERNANDO HERNANDEZ, individually and as next friend and executor of the estate of KATHERINE HERNANDEZ, deceased,	)	
Plaintiff,	)	Case No. 15 C 11176
v.	)	
	)	Judge Robert W. Gettleman
WYETH-AYERST LABORATORIES, INC.; SANDOZ INC.; and EON LABS, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Fernando Hernandez has brought a wrongful death claim on behalf of the estate of his wife, Katherine Hernandez, against defendants for injuries she sustained after taking a prescription drug, amiodarone hydrochloride ("amiodarone"). Defendants Sandoz Inc. and Eon Labs, Inc. ("Sandoz")[1] moved to dismiss the complaint under Federal Rules of Civil Procedure 12(b)(6) and 8(a)(2). For the reasons described below, defendant's motion is granted in part and denied in part.

BACKGROUND[2]

Wyeth-Ayerst received approval from the Food and Drug Administration ("FDA") to market and sell amiodarone (which it sold under the brand name Cordarone) in late December of

[1] Eon was acquired by Sandoz in 2005 and is a wholly owned subsidiary of Sandoz. For simplicity's sake, the court will refer to both defendants jointly as Sandoz. It appears from the record that Wyeth-Ayerst has not been served.

[2] The following facts are taken from plaintiff's complaint and are assumed to be true for purposes of this motion to dismiss. See Murphy v. Walker, 51 F.3d 714, 717 (7th Cir. 1995).

1985. Wyeth-Ayerst was authorized to market and sell amiodarone only as a drug of last resort for patients suffering from life-threatening ventricular fibrillation and ventricular tachycardia, and only when those patients did not respond to other drugs and therapies. Sandoz received FDA approval to market, sell, and distribute the generic formulation of the drug in 1998.[3] As a generic manufacturer of amiodarone, Sandoz is required to comply with the same FDA requirements as Wyeth-Ayerst. Specifically, under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq., Sandoz has a "duty of sameness," which requires it to ensure that its labeling is identical to Wyeth-Ayerst's FDA-approved labeling. The FDCA also requires manufacturers of certain drugs (brand-name or generic) to provide medication guides to their distributors, who are then required to provide them to people whose prescriptions those distributors fill. Amiodarone is one of those drugs. As with labeling, the medication guides provided for generic drugs must be identical to those provided for the brand-name counterparts. Medication guides are provided to patients to explain the permissible uses of a drug and the consequences of misusing it "in plain English."

Plaintiff alleges that Sandoz violated the FDCA in two ways. First, plaintiff alleges that Wyeth-Ayerst and Sandoz "embarked on a course of conduct, the purpose of which was to increase amiodarone sales as an initial, first-line anti-arrhythmic medication, a use for which amiodarone has never received FDA approval; i.e., an 'off-label' use." Plaintiff alleges that Sandoz, along with Wyeth-Ayerst, aggressively marketed amiodarone for off-label use despite their knowledge that such use posed serious health risks and without informing physicians or

[3] Eon received FDA approval to manufacture amiodarone in 1998 and transferred that approval to Sandoz when it was acquired by Sandoz in 2005.

patients of those risks, as required by the FDCA. Next, plaintiff alleges that Sandoz violated the FDCA by failing to provide distributors of amiodarone with medication guides.

Plaintiff's wife had been diagnosed with non-life-threatening atrial fibrillation when she was prescribed a 90-day course of 200mg amiodarone tablets in May 2013.[4] According to plaintiff, the prescribing doctors were victims of Sandoz's scheme to aggressively market amiodarone for off-label use, and they would not have prescribed the drug had they been informed of the risks associated with such use. Plaintiff further alleges that his wife was also unaware of the risks associated with amiodarone because she never received a medication guide. Plaintiff claims that his wife would not have taken amiodarone if she had known the risks.

According to plaintiff, his wife began to suffer many of amiodarone's unfortunate side effects after she started taking it. Those side effects are outlined in the medication guide, which she never received, and include: shortness of breath; wheezing; trouble breathing; coughing; tiredness; weakness; nervousness; irritability; restlessness; decreased concentration; and depression. Plaintiff alleges that his wife's condition continued to deteriorate as she continued to take amiodarone until she was diagnosed with amiodarone toxicity on September 26, 2013, after which she stopped taking it. Plaintiff further alleges that the amiodarone remained in his wife's body after she stopped taking it, and that she suffered with recurring pneumonia and severe lung damage until she died from amiodarone-induced lung disease on November 3, 2013.[5]

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[4] Plaintiff alleges that his wife was first given amiodarone manufactured by Wyeth-Ayerst, which he mistakenly refers to as Pacerone rather than Cordarone, when she was in the hospital in May 2013. She then filled a prescription for generic amiodarone, manufactured by Sandoz, which she took after leaving the hospital.

[5] In his response, plaintiff claims that his wife died on November 19, 2012. Because the

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DISCUSSION

I. Legal Standard

A motion brought under Rule 12(b)(6) challenges the sufficiency of the complaint. Hallinan v. Fraternal Order of Police of Chi. Lodge No. 7, 570 F.3d 811, 820 (7th Cir. 2009). Under Rule 8(a)(2), a complaint must include a short and plain statement of the claim showing that the pleader is entitled to relief. Fed.R.Civ.P. 8(a)(2). The pleading must describe the claim in sufficient detail to give the defendant fair notice of what the claim is and the grounds on which the claim rests. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). The allegations must plausibly suggest that the plaintiff has a right to relief, raising the possibility above the "speculative level." Id.

This standard demands that a complaint contain sufficient factual matter to state a claim that is plausible on its face and allege more than legal conclusions or "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "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." Id. When ruling on a Rule 12(b)(6) motion to dismiss, the court accepts the complaint's well-pleaded factual allegations as true and draws all reasonable inferences in the plaintiff's favor. Sprint Spectrum L.P. v. City of Carmel, Indiana, 361 F.3d 998, 1001 (7th Cir. 2004).

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court decides a motion to dismiss based on the allegations in the complaint, its analysis will assume that the date listed in the complaint is correct.

II. Analysis

Sandoz argues for dismissal on a number of grounds. Sandoz first argues that plaintiff's complaint should be dismissed because it was not filed within the time allowed by the statute of limitations. Next, Sandoz argues that plaintiff's claims are preempted by federal law. Finally, Sandoz argues that plaintiff's claims are insufficiently pled. The court will address these arguments in turn.

A. Statute of Limitations

According to the complaint, which was filed on December 11, 2015, plaintiff's wife died on November 3, 2013. Under Illinois law, personal injury claims must be brought within two years of the injury. See 735 ILCS 5/13-202. Sandoz points out that the complaint was filed more than two years after plaintiff's wife passed away and argues that this is grounds for dismissal. Plaintiff argues that his claims are not time-barred because he did not know the cause of his wife's death until he received the death certificate several weeks later. Sandoz acknowledges that the clock begins to run on the statute of limitations "when the plaintiff possesses sufficient knowledge of his injury and its cause such that would place a reasonable person on notice to ascertain its source and whether legally actionable conduct was involved." Healy v. Owens-Illinois, Inc., 359 Ill. App. 3d 186, 194 (1st Dist. 2005). Accordingly, Sandoz argues that plaintiff's knowledge that his wife was diagnosed with amiodarone toxicity in September 2013 coupled with her death in November 2013 was sufficient to put him on notice of the cause of her death. This argument ignores the alleged fact that plaintiff's wife stopped using the amiodarone more than a month before her death, and that plaintiff first learned of the cause of death from the death certificate less than two years from filing this lawsuit. There is, at the

very least, a disputed question of fact as to when plaintiff possessed sufficient knowledge of the cause of his wife's death. For that reason, dismissal is not appropriate. See id. Sandoz's motion is denied as to the statute of limitations.

B. Preemption

Next, Sandoz argues that plaintiff's complaint should be dismissed because his claims are either expressly or impliedly preempted by federal law. Sandoz first attacks plaintiff's duty to warn claim, largely relying on PLIVA v. Mensing, 564 U.S. 604 (2011), to argue that federal law expressly preempts all state law tort claims attacking the sufficiency of warnings provided by generic drug manufacturers. But, as plaintiff points out, Mensing held that state tort law is preempted only where it conflicts with federal law because it is "impossible for a private party to comply with both state and federal requirements," Id. at 618. That is not the case here, and Sandoz does not argue that it is.

In Mensing, the Court analyzed the tort laws of two states: Minnesota and Louisiana. The Mensing parties agreed that under those states' laws the manufacturers of the generic version of the drug metoclopramide would have been required to include a warning on the label that long term use increased the risk of a condition called tardive dyskinesia, if they were aware of the risk. Id. at 612. The FDA-approved metoclopramide label contained no such warning. The Court noted the "duty of sameness" borne by generic drug manufacturers: federal law "demand[s] that generic drug labels be the same at all times as the corresponding brand-name drug labels." Id. at 618 (citing 21 C.F.R. § 314.150(b)). Because the generic metoclopramide manufacturers could not possibly comply with the state tort laws while also fulfilling their federal duty of sameness, the state laws were preempted. Id. at 624. Where, however, it is

possible to comply with both state and federal law, state tort law is not preempted. Id. (citing Wyeth v. Levine, 555 U.S. 555 (2009)).

Here, plaintiff alleges that Sandoz violated its duty to warn under Illinois law *because* it violated the FDCA's requirement to provide distributors with medication guides. Additionally, plaintiffs do not allege that the information in Sandoz's medication guides is insufficient, but rather that it is unavailable. Although the duty to provide a medication guide arises solely under federal law, the duty to warn does not, and a state law claim is not preempted where state duties "'parallel,' rather than add to, federal requirements." Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010) (quoting Riegel v. Medtronic, 552 U.S. 312, 330 (2008)). Because plaintiff's duty to warn claim parallels the FDCA requirement to supply distributors with medication guides, it is not expressly preempted. Sandoz cites to a number of opinions that have held otherwise, but those decisions from outside the Seventh Circuit are not binding on this court. Bausch is. Sandoz's motion as to that claim is denied.

The same can be said for plaintiff's claim that Sandoz was negligent under Illinois law for advertising amiodarone for off-label use despite the risks such use presented. Plaintiff may rely on this alleged violation of the FDCA as evidence of his Illinois common law negligence claim provided that he "does not claim that the state law imposes an additional requirement on [defendants]." Garross v. Medtronic, Inc., 77 F.Supp.3d 809, 815–16 (E.D. Wis. Jan. 21, 2015). Because plaintiff makes no such claim, Sandoz's motion as to that claim is denied.

Next, Sandoz relies on Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), to argue that plaintiff's off-label and medication guide claims are impliedly preempted because they depend on alleged violations of a duty that only the federal government may enforce. The

Seventh Circuit analyzed a very similar argument in Bausch, 630 F.3d 546, and found it unconvincing. In Bausch the court noted that the Buckman Court distinguished between claims that a manufacturer made fraudulent misrepresentations to the FDA, or "fraud-on-the-agency" claims, which are impliedly preempted, and claims based on state law tort principles, which are not. Bausch, 630 F.3d at 558. For the latter claims, courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Id. (internal quotation omitted). The Seventh Circuit found "no indication that Congress intended preemption of state claims based on violations of federal law" except where such "limitations [are] set forth in [an] express preemption clause" and no implied preemption where state law claims do not conflict with federal regulations. Id. Sandoz does not cite to an applicable express preemption clause, and the state law claims in the instant case do not conflict with federal law, as discussed above. Accordingly, plaintiff's state law claims are not impliedly preempted and Sandoz's motion is denied on preemption grounds.

Sandoz's final argument in favor of preemption is that, even if state law claims that parallel federal requirements are not preempted, plaintiff has failed to identify duties under Illinois law that parallel the FDCA's requirements. That argument will be addressed below.

C. Sufficiency and Plausibility of Plaintiff's Claims

As an initial matter, Sandoz correctly notes that plaintiff has violated Local Rule 7.1 by "incorporating" Section III of his response to Sandoz's original motion to dismiss (doc. 56) into his response to the instant motion. By doing this, plaintiff has exceeded the fifteen page limit without prior approval of the court, as required. See L.R. 7.1. Although the court could, in its

discretion, disregard plaintiff's incorporated arguments due to this violation, Sandoz has responded and the court will address the parties' arguments.

Sandoz argues that plaintiff's claims run afoul of Rule 8(a)(2) because they are, in general, speculative and conclusory allegations that lack factual support, and because plaintiff "lumps together" all of the defendants without identifying which allegations apply to each. Sandoz further argues that plaintiff's off-label promotion claims are premised upon alleged fraud or misrepresentation and fail to satisfy the heightened pleading standards of Fed. R. Civ. P. 9(a). The court will address these arguments in turn.

First, the court finds no issue with plaintiff's making some allegations against the defendants as a group. Plaintiff has sufficiently alleged that all of the defendants acted in concert in promoting amiodarone for off-label uses, in which case they should be grouped. See Birchmeier v. Caribbean Cruise Line, Inc., 2012 WL 7062748 (N.D.Ill. Dec. 31, 2012) (Rejecting the argument that Rule 8 prohibits allegations against defendants as a group where the plaintiff alleges that the defendants acted in concert.). Additionally, although not a model of clarity, the complaint seems to allege that only Sandoz is responsible for failing to supply medication guides to his wife's pharmacy, as required by the FDCA. The complaint alleges that plaintiff's wife did not receive the medication guide from "defendants" for prescriptions she filled at an unspecified Walgreens. The complaint also alleges that Sandoz manufactured the amiodarone that was used to fill that prescription. It follows, then, that this particular allegation is directed to Sandoz.[6]

[6] If plaintiff chooses to amend his complaint, he should consider clarifying this allegation in order to streamline future litigation. Additionally, the court notes that the complaint alleges

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As for plaintiff's claim that Sandoz violated its duty to warn under Illinois law by violating the FDA's requirement to provide distributors of amiodarone with medication guides, Sandoz argues that plaintiff's claims consist of nothing more than conclusory and speculative allegations. Plaintiff, relying on a Report and Recommendation in a case before the United States District Court for the Western District of Texas, argues that he need only claim that the pharmacy that filled his wife's prescription was unable to give her a medication guide because Sandoz failed to supply one to sufficiently plead this allegation. See Rusk v. Wyeht-Ayerherst Laboratories, Inc., 2015 WL 3651434 (W.D. Tex. June 11, 2015), adopted sub nom. Rusk v. Wyeth-Ayerherst Laboratories, Inc., (W.D. Tex. Oct. 26, 2015). This court is not persuaded by that court's analysis and is not bound by it. An allegation that the pharmacy that filled plaintiff's wife's prescription was unable to give her a medication guide because Sandoz failed to provide one is an allegation that Sandoz violated the FDCA, not Illinois common law. That said, the court finds that plaintiff has sufficiently pled his failure to warn claim.

To establish a failure to warn claim against a drug manufacturer under Illinois law, plaintiff must allege that: "(1) Defendants had a duty to warn; (2) Defendants knew or should have known of the danger but failed to warn Plaintiff of the fact; (3) the omission of such information made the warning inadequate and the drug defective; and (4) the defect proximately caused Plaintiff's injury." Engelhard v. Wyeth Consumer Healthcare Ltd., 2015 WL 1159442, at *2 (N.D. Ill. Mar. 11, 2015). Plaintiff's complaint alleges that Sandoz had a duty to provide

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that Wyeth-Ayerst is also responsible for failing to provide medication guides. That allegation is based on plaintiff's claim that his wife received amiodarone that was manufactured by Wyeth-Ayerst while she was in the hospital without being provided a medication guide. Because Wyeth-Ayerst has not responded to that claim, the court will not address it.

adequate warnings for amiodarone, that Sandoz was aware of the risks associated with off-label use, that his wife was not warned of these risks, which ultimately resulted in her death, because she did not receive a medication guide, and that she did not receive a medication guide because Sandoz failed to provide them to the pharmacy that filled his wife's prescription. Although plaintiff focuses much of his complaint on his allegations that Sandoz's actions violated the FDCA, he has sufficiently alleged each of the elements necessary to establish a failure to warn claim under Illinois law.

As for plaintiff's claim that Sandoz promoted amiodarone for off-label use, assuming that it is based in negligence,[7] plaintiff must allege that Sandoz owed him a duty, breached that duty, and injury resulted to establish a valid claim under Illinois law. See Tillman v. Taro Pharm. Indus. Ltd., 2011 WL 3704762 at *5 (N.D.Ill. Aug. 17, 2011) (citing Lewis v. CITGO Petroleum Corp., 561 F.3d 698, 702 (7th Cir. 2009)). Plaintiff's complaint alleges that Sandoz violated FDA regulations by engaging in a scheme to persuade doctors to prescribe amiodarone for off-label use, despite knowing that such use was not FDA-approved and would result in harm, and without any concern for the harm that patients like plaintiff's wife would suffer. Although plaintiff again focuses much of his complaint on his allegations that Sandoz's actions violated the FDCA, he has sufficiently pled that Sandoz was negligent under Illinois law when it promoted amiodarone for off-label use. Accordingly, Sandoz's motion is denied as to that claim.

[7] In his response, plaintiff asks the court to analyze his off-label marketing claim as a negligence claim if it finds that he has not alleged sufficient facts to comply with Rule 9(b). Because the court so finds (discussed below), the court proceeds as though the claim is based in negligence. Additionally, in his complaint plaintiff alleges that Wyeth-Ayerst is liable to plaintiffs under the following theories: strict liability, negligence per se, negligence, and gross negligence. Because plaintiff makes no such claim as it relates to Sandoz, the court will not address whether these theories apply to Sandoz.

Assuming plaintiff's claim that Sandoz promoted amiodarone for off-label use is a fraudulent misrepresentation claim, Sandoz argues that it fails to meet Rule 9(b)'s heightened pleading standard. The court agrees. A complaint alleging fraud must comply with Rule 9(b). Bietsch v. Sergeant's Pet Care Products, Inc., 2016 WL 1011512, at *3 (N.D. Ill. Mar. 15, 2016). "To meet the particularity requirements of Rule 9(b), a complaint must specify the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff." Sears v. Likens, 912 F.2d 889, 893 (7th Cir. 1990). Plaintiff's claim that "defendants pushed amiodarone" as a "drug suitable as an initial therapy and to treat non-life threatening heart conditions" fails to satisfy these requirements. Plaintiff argues that his fraudulent misrepresentation claim should not be dismissed because "Rule 9(b) is satisfied by a showing that further particulars of the alleged fraud could not have been obtained without discovery." Emery v. Am. Gen. Fin., Inc., 134 F.3d 1321, 1323 (7th Cir. 1996). Be that as it may and assuming that plaintiff has made such a showing, the complaint does not lack *further* particulars of the alleged fraud, it lacks *any* particulars. Consequently, Sandoz's motion is granted without prejudice as to plaintiff's fraudulent misrepresentation claim.

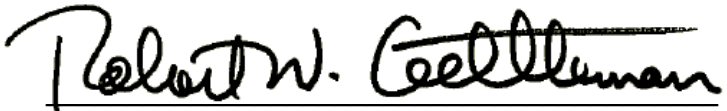
On a final note, the court disagrees with Sandoz's argument that plaintiff's allegations are not plausible. A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. Plaintiff alleges that Sandoz intentionally marketed amiodarone for off-label use, knowing the risks associated with that use, and that it did not provide medication guides to his wife's pharmacy to ensure that she was aware of those risks before she took

amiodarone for such use. Plaintiff further alleges that his wife would not have suffered the amiodarone-induced injuries that resulted in her death if she had known the risks beforehand because she would not have taken it. Taking these allegations as true and construing all facts in favor of the plaintiff, as the court must, plaintiff's claims are plausible, even if not well pled. Whether plaintiff's claims are in fact true is not an issue to be decided in a motion to dismiss. Pearson v. Target Corp., 2012 WL 7761986, at *2 (N.D. Ill. Nov. 9, 2012).

CONCLUSION

For the foregoing reasons, Sandoz's motion to dismiss is granted without prejudice with respect to plaintiff's claims regarding fraudulent promotion of amiodarone for off-label uses, and denied in all other respects. This motion is set for a status hearing on April 25, 2017, at 9:00 a.m., at which plaintiff shall inform the court whether he wishes to file an amended complaint conforming with this opinion.

ENTER: April 18, 2017



Robert W. Gettleman
United States District Judge