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
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. ("defendant")[1] moved to dismiss the complaint under Federal Rules of Civil Procedure 12(b)(6) and 8(a)(2). The court granted that motion in part and denied it in part on April 18, 2017. Defendant filed a motion to reconsider, to which plaintiff, for some unexplained reason, chose not to respond.[2] For the reasons discussed below, that motion is granted in part and denied in part.

The court assumes familiarity with its April 18, 2017, opinion, which discussed the facts of the case at length, and will not recite them here. The court may revise any judgment that does not adjudicate all of the claims and all of the parties' rights and liabilities. Fed. R. Civ. P. 54(b).

[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 "defendant."

[2] Despite the court's May 10, 2017, order setting a briefing schedule for the instant motion, plaintiff's counsel chose not to inform the court of his decision not to file a responsive brief. Such acts of discourtesy are unprofessional and will not be tolerated in the future.

A motion to reconsider may not introduce new issues or re-try arguments previously rejected. Lock Realty Corp. IX v. U.S. Health, LP, 2010 WL 148296, at *1 (N.D. Ind. Jan. 13, 2010), aff'd, 707 F.3d 764 (7th Cir. 2013). Defendant argues that the court has made an error of apprehension with respect to three issues: (1) its treatment of plaintiff's off-label promotion claim as a negligence claim; (2) its interpretation of Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010); and (3) its conclusion that plaintiff's medication guide claim is parallel to an Illinois common law duty to warn claim. The court will address these arguments in turn.

I. Plaintiff's Off-Label Promotion Claim Is a Fraudulent Misrepresentation Claim

In its motion to dismiss, defendant argued that plaintiff's off-label promotion claim sounds in fraud and fails to satisfy the particularity requirements of Rule 9(b). Plaintiff countered (in responding to the original motion to dismiss) that he has satisfied Rule 9(b) because his complaint contains some allegations made with particularity and makes a showing that further particulars of the alleged fraud cannot be obtained without discovery. The court rejected that argument, finding that the complaint lacked any particulars of the allegedly fraudulent scheme. Plaintiff further argued, however, that if his off-label promotion claim did not satisfy Rule 9(b), it should survive as a negligence claim because it satisfies Rule 8(a)(2). Defendant did not oppose this proposal in its reply brief, and the court proceeded to analyze the claim as a negligence claim, in part because plaintiff styled it as such in paragraph 121 of his complaint. Defendant now argues that the court was wrong to analyze plaintiff's off-label promotion claim as a negligence claim for two reasons.

First, plaintiff argues that other paragraphs of plaintiff's complaint make clear that plaintiff attempts, but fails, to assert a fraudulent misrepresentation claim. Second, plaintiff

argues that the court misapprehends the case it cites to support the proposition that plaintiff may plead a negligence claim for off-label promotion. The court agrees with defendant's first point. Plaintiff's complaint is a sprawling and, at times, confusing collection of largely unnecessary allegations that, for the most part, seem to attempt to assert a fraudulent misrepresentation claim as it relates to off-label promotion. Although plaintiff is entitled to plead in the alternative, in doing so his pleadings must be "simple, concise and direct." Fed. R. Civ. P. 8(d)(1)–(2). Even construing his complaint generously, plaintiff's off-label promotion claim is none of these. Accordingly, defendant's motion is granted without prejudice as to plaintiff's off-label promotion claim, and plaintiff is granted leave to file an amended complaint conforming with this opinion.

As for defendant's second argument, it is defendant who misapprehends the court's opinion. Defendant failed to respond to plaintiff's suggestion that the court analyze his off-label promotion claim as a negligence claim, and the court took no position as to that claim beyond the sufficiency of the pleading. The court had no reason to cite Tillman v. Taro Pharm. Indus. Ltd., 2011 WL 3704762, *5 (N.D. Ill. Aug. 17, 2011), to support the proposition that plaintiff may plead a negligence claim for off-label promotion, and did no such thing. The court cited Tillman only for its discussion of the elements necessary to establish an Illinois law negligence claim, nothing more.

II. Bausch is Applicable to the Instant Case

Next, defendant argues that the court misapprehends the scope of Bausch. In its motion to dismiss, defendant argued that plaintiff's claims are preempted by federal law. Plaintiff argued that his Illinois law claims are not preempted because they are parallel to, and do not

conflict with, federal law. The court agreed with plaintiff and in doing so, as defendant points out in its motion to reconsider, disregarded the positions of several far-ranging district courts and instead relied on Seventh Circuit precedent established in Bausch, 630 F.3d 546. Defendant now argues that the court has misapprehended the scope of Bausch. The court disagrees.

As an initial matter, because plaintiff, for some reason, failed to respond to defendant's motion, even when invited to by the court, plaintiff has made the court's work in ruling on the motion significantly more difficult. And yet, the court's own research has revealed at least two recent district court cases within the Seventh Circuit that have interpreted Bausch precisely as this court did in its opinion.[3] See In re Testosterone Replacement Therapy Products Liab. Litig. Coordinated Pretrial Proceedings, 2017 WL 1836443, at *7 (N.D. Ill. May 8, 2017) (citing Bausch for the proposition that only "fraud-on-the-agency claims, i.e., claims not related to a field of law that states traditionally occupied" are preempted, and finding that claims similar to those in the instant case, including failure to warn, are not preempted "because the claims are grounded in traditional state law principles of liability") (internal quotations omitted); Marvin v. Zydus Pharmaceuticals Inc., 203 F. Supp. 3d 985, 988 (W.D. Wis. 2016) (citing Bausch as "explaining that [a] state law claim arising solely from [a] violation of federal requirements is impliedly preempted but one alleging breach of a well recognized duty owed to plaintiff under state law survives implied preemption") (internal quotation omitted). Neither of these cases involved a medical device and, in fact, Zydus Pharmaceuticals involved the exact same drug that is at issue in the instant case. In light of this persuasive authority, the court rejects defendant's

[3] The court notes that both of these cases also cite Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), which defendant relies on heavily, to support their conclusion that the plaintiffs' state law claims were not preempted.

argument that Bausch is inapplicable to generic drug claims because the claim at issue in Bausch involved a medical device. Simply put, the reasoning in Bausch that led the court to conclude that state law claims are not preempted where they are grounded in traditional state law principles of liability and do not conflict with federal law extends to generic drug claims.

Additionally, in Zydus Pharmaceuticals, the court found that "a number of federal circuit courts considering the issue have held or noted in dicta that state claims based on violations of the Food, Drug and Cosmetics Act are not impliedly preempted." 203 F. Supp. 3d at 988 (citing McClellan v. I-Flow Corp., 776 F.3d 1035, 1041 (9th Cir. 2015); Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 586–87 (6th Cir. 2013); Hughes v. Boston Scientific Corp., 631 F.3d 762, 775 (5th Cir. 2011); In re Orthopedic Bone Screw Products Liability Litigation, 193 F.3d 781, 791 (3d Cir. 1999)). Because it was binding on the court, the court found that Bausch was "most instructive." Id. After an extensive review of the landscape regarding state law claims that parallel, and do not conflict with, claims based on the FDCA, the court is convinced that it did not err in allowing plaintiff's Illinois law-based failure to warn claim to proceed. Defendant's motion is denied on this ground.

III. Plaintiff's Medication Guide Claim is Parallel to an Illinois Common Law Duty to Warn Claim

In its motion, defendant argues that the court misapprehended "the difference between the purported federal law violations Plaintiff alleges and the Illinois common law failure to warn claim on which this Court's ruling relied." According to defendant, "in order for a parallel state law claim to exist, the state law failure to warn duty must require that the drug manufacturer provide ***pharmacists*** with warnings to pass on to consumers." (emphasis supplied). The court

rejects defendant's cramped interpretation of a parallel Illinois common law failure to warn claim.

As the court explained in its April 18, 2017, opinion, 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;[4] (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) (citations omitted). Plaintiff's complaint alleges that defendant had a duty to provide adequate warnings for amiodarone, that defendant was aware of the risks associated with off-label use, that his wife was not warned of those 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 defendant failed to provide them to the pharmacy that filled his wife's prescription. Plaintiff further alleges that his wife's physicians did not and could not warn her of the risks associated with off-label use because defendant failed to inform the physicians of those risks. The court remains convinced that plaintiff has sufficiently alleged each of the elements necessary to establish a failure to warn claim under Illinois law despite focusing much of his complaint on his allegations that defendant's actions violated the FDCA.[5]

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[4] Because the instant case involves a prescription drug, defendant had a duty to warn the prescribing physicians of the risks associated with off-label use. In re Depakote, 2015 WL 4776093, at *3 (S.D. Ill. Feb. 14, 2015) (citing Northern Trust Co. v. Upjohn Co., 572 N.E.2d 1030, 1037 (Ill.App.Ct. 1991)).

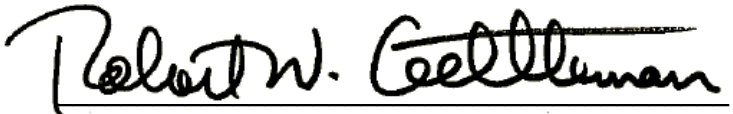
[5] The court encourages plaintiff to streamline his amended complaint to focus only on the

continue...

CONCLUSION

For the foregoing reasons, defendant's motion to reconsider is granted without prejudice with respect to plaintiff's claims regarding fraudulent promotion of amiodarone for off-label use, and denied in all other respects. Plaintiff is directed to file an amended complaint on or before August 21, 2017. This matter remains set for a report on status on August 31, 2017, at 9:00 a.m.

ENTER: August 1, 2017



Robert W. Gettleman
United States District Judge

[5]...continue
issues that the court finds are not preempted in order to simplify future litigation.