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

LAWRENCE LEMPA, as Independent Executor of the Estate of LINDA LEMPA,	)	
Plaintiff,	)	No. 18 C 3821
v.	)	Judge Edmond E. Chang
EON LABS, INC. and SANDOZ, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Linda Lempa suffered from a non-life-threatening heart condition called atrial fibrillation.[1] R. 1.2, Compl. ¶ 11.[2] In November 2012, Linda's doctor prescribed her amiodarone, a drug manufactured by Defendant Sandoz, Inc., to treat her condition. *Id.* ¶ 12. Several months later in March 2013, Linda passed away from acute hypoxic respiratory failure. *Id.* ¶¶ 19-21. Linda's husband, Lawrence Lempa, now brings this claim against Sandoz alleging that amiodarone was the direct and proximate cause of Linda's death. *Id.* ¶ 31. He alleges that Sandoz breached its duty to warn Linda about the risks associated with taking amiodarone as a "first line" treatment for non-life-threatening conditions—a use for which it was not approved by the FDA—and negligently promoted the drug for this off-label use. *Id.* ¶¶ 7-10, 30. He also alleges

[1]This Court has subject matter jurisdiction over these state law tort claims under 28 U.S.C. § 1332. Plaintiff Lawrence Lempa is a citizen of Illinois. R. 1.2, Compl. ¶ 1. Defendant Sandoz, Inc. is a citizen of Colorado and New Jersey, *id.* ¶ 3; R. 1, Notice of Removal ¶ 13, while Defendant Eon Labs, Inc. is a citizen of Delaware and New York, *id.* ¶ 14.

[2]Citations to the docket are noted by "R." followed by the docket entry and page or paragraph number.

that Sandoz failed to provide Medication Guides in violation of FDA regulations. *Id.* ¶¶ 26-29. He brings claims for failure to warn, negligence per se, and fraudulent concealment on behalf of himself and Linda. Sandoz and its predecessor, Eon Labs, Inc., now move to dismiss the Complaint. For the reasons explained below, the motion is granted in part and denied in part.

I. Background

For the purposes of this motion, the Court accepts as true the allegations in the Amended Complaint. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). Amiodarone is a prescription medication used as drug of last resort to treat certain heart conditions, such as ventricular fibrillation and ventricular tachycardia. Compl. ¶ 8. The brand-name version of amiodarone is called Cordarone® and was approved by the FDA in 1985. Compl. ¶ 7; Mtn. Dismiss at 4. Eon Labs, Inc. (Eon) received approval from the FDA to sell the generic formulation—amiodarone—in 200 mg tablets in 1998. Mtn. Dismiss at 5. In 2005, Sandoz, Inc. acquired Eon Labs, Inc., and since then has continued to manufacture and sell amiodarone in 200 mg tablets. R. 15, Defs.' Answer ¶ 7.

Amiodarone is approved by the FDA only to treat recurrent, life-threatening heart conditions, and only once all other forms of treatment have failed. Compl. ¶ 8. Nonetheless, the medication is sometimes prescribed as a "first line" treatment for other heart conditions, like atrial fibrillation. *Id.* ¶ 10. Lempa also alleges that Sandoz promotes these "off-label" uses of amiodarone and does not warn prescribing physicians of the dangers associated with using the medication to treat non-life-threatening heart conditions. *Id.* ¶¶ 9-10.

In November 2012, Linda Lempa (Linda) was diagnosed with atrial fibrillation, a non-life-threatening heart condition. Compl. ¶ 11. At the time, she was in good pulmonary health and suffered from no underlying respiratory issues or conditions. *Id.* ¶ 22. Her cardiologist at the time. Dr. Peter Kakavas, prescribed 200 mg of amiodarone, to be taken twice a day for 30 days, to treat her atrial fibrillation. *Id.* ¶ 12. Lempa alleges that Linda never received a Medication Guide—a document that explains the risks associated with the medication—with her prescription, nor any other type of warning from her doctor or pharmacist. *Id.* ¶¶ 16, 29, 30. On February 18, 2013, Linda began to experience shortness of breath and labored breathing, and, two days later, she was admitted to a local hospital with potential pneumonia or pulmonary fibrosis. *Id.* ¶ 17. Linda was again given amiodarone while hospitalized. *Id.* ¶ 18. Several days later, she was diagnosed with acute respiratory failure, at which point her doctors intubated her and discontinued the amiodarone. *Id.* ¶ 19. Linda's condition continued to decline nonetheless, and she was eventually transferred to Rush University Hospital, where she passed away from hypoxic respiratory failure on March 4, 2013. *Id.* ¶¶ 20, 21.

Lempa sued Sandoz, Eon, and several other defendants in the Circuit Court of Cook County, Illinois on March 6, 2018. Notice of Removal ¶ 1. The other defendants were eventually all voluntarily dismissed by Lempa. *Id.* ¶¶ 2, 8. Sandoz and Eon (collectively, Sandoz) successfully removed the suit to this Court. *Id.* at 1. In his Complaint, Lempa alleges that amiodarone caused Linda's death from acute hypoxic respiratory failure, and that Sandoz is liable for failing to warn her of the

risks associated with the drug's off-label uses. Compl. ¶¶ 20-21, 30-31, 36-37. Sandoz now moves to dismiss Lempa's complaint as untimely, preempted by federal law, and insufficiently pled. Mtn. Dismiss at 1-2.

II. Legal Standard

Under Federal Rule of Civil Procedure 8(a)(2), a complaint generally need only include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This short and plain statement must "give the defendant fair notice of what the … claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (cleaned up).[3] The Seventh Circuit has explained that this rule "reflects a liberal notice pleading regime, which is intended to 'focus litigation on the merits of a claim' rather than on technicalities that might keep plaintiffs out of court." *Brooks v. Ross*, 578 F.3d 574, 580 (7th Cir. 2009) (quoting *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514 (2002)).

"A motion under Rule 12(b)(6) challenges the sufficiency of the complaint to state a claim upon which relief may be granted." *Hallinan v. Fraternal Order of Police of Chi. Lodge No. 7*, 570 F.3d 811, 820 (7th Cir. 2009). "[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) (quoting *Twombly*, 550 U.S. at 570). These allegations "must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. The allegations that are entitled to the

[3]This opinion uses (cleaned up) to indicate that internal quotation marks, alterations, and citations have been omitted from quotations. *See* Jack Metzler, *Cleaning Up Quotations*, 18 Journal of Appellate Practice and Process 143 (2017).

assumption of truth are those that are factual, rather than mere legal conclusions. *Iqbal*, 556 U.S. at 678-79.

III. Analysis

A. Statute of Limitations

Sandoz begins its Motion to Dismiss by arguing that Lempa's claims are barred by the statute of limitations, because they were filed "more than two years after his causes of action accrued" at the time of Linda's death on March 4, 2013. Mtn. Dismiss at 6. Sandoz also asserts that neither the discovery rule nor fraudulent concealment saves Lempa's claims, because Lempa "does not allege or plead that he was unable to determine the cause of his wife's death before the statute of limitations expired." *Id.* at 7. Lempa responds by pointing out that the statute of limitations is an affirmative defense,[4] making dismissal on those grounds inappropriate, and arguing that his claims are subject to the continuing violations doctrine because Sandoz is "engaged and [is] still engaging in a continuous course of negligent conduct." R. 26, Pl.'s Resp. at 3-4.

Lempa's first argument is correct. The statute of limitations is indeed an affirmative defense, and a complaint need not plead around it in order to survive dismissal. *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., Inc.*, 782 F.3d 922, 928 (7th Cir. 2015). And, "[u]nless the complaint alleges acts that create an ironclad defense, a limitations argument must await factual development." *Foss v.*

[4]Although this argument is barely developed in Lempa's response, he has not waived it. He clearly states that "[i]n Illinois, the statute of limitations is an affirmative defense," and argues that he has not pled himself out of court, making dismissal for untimeliness inappropriate at this stage. Pl.'s Resp. at 3-4.

Bear, Stearns & Co., Inc., 394 F.3d 540, 542 (7th Cir. 2005); *see also Chi. Bldg. Design, P.C. v. Mongolian House, Inc.*, 770 F.3d 610, 613-14 (7th Cir. 2014) (explaining that dismissal is appropriate "only where the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense") (cleaned up).

Here, Lempa's allegations do not establish with certainty that his claims are untimely. The Complaint certainly raises questions about the timeliness of the claims, given the two-year statute of limitations for personal injury claims under Illinois law. *See* 735 ILCS 5/13-202. But it also does not rule out a set of facts that could defeat a statute of limitations defense. Indeed, Lempa alleges that he and Linda had no knowledge she was being prescribed amiodarone for an off-label use and were "unaware of the potential life-threatening complications of amiodarone." Compl. ¶¶ 13-14. Lempa presumably discovered these facts later on, and that might serve to toll the statute of limitations (right now, the Court does not express an opinion on this one way or the other). *See Golla v. Gen. Motors Corp.*, 657 N.E.2d 894, 898 (Ill. 1995) (explaining that the discovery rule postpones "the commencement of the relevant statute of limitations until the injured plaintiff knows or reasonably should know that he has been injured and that his injury was wrongfully caused"); *Mitsias v. I-Flow Corp.*, 959 N.E.2d 94, 99-100 (Ill. App. Ct. 2011) (applying discovery rule to product-liability action).

This is all that is required of Lempa at the pleading state, despite Sandoz's assertion that Lempa needed to "allege or plead that he was unable to determine the cause of his wife's death before the statute of limitations expired." Mtn. Dismiss at 7.

As already mentioned, pleading around a defense of untimeliness is not required under the Federal Rules of Civil Procedure. And, because there is a set of facts that if proven would establish Lempa's claims as timely, they will not be dismissed on these grounds. *See Clark v. City of Braidwood*, 318 F.3d 764, 768 (7th Cir. 2003) (reversing dismissal because, "at this stage, the question is only whether there is *any* set of facts that if proven would establish a defense to the statute of limitations, and that possibility exists" (emphasis in original) (citation omitted)); *Early v. Bankers Life & Cas. Co.*, 959 F.2d 75, 80 (7th Cir. 1992) ("[W]hen a complaint is dismissed at the pleadings stage the question is not what are the facts, but is there a set of facts that if proved would show that the case had merit?").

Lempa should not confuse this holding as either an explicit or implicit adoption by the Court of the continuing-violations argument he made in the response brief. That doctrine is inoperative here. Regardless of Sandoz's behavior towards *others*, its interaction with Lempa ceased when Linda died—and discontinued using amiodarone—in March 2013, which is also when Lempa suffered his injury. *Tuduj v. Sanofi-Aventis U.S. LLC*, 721 F. App'x 496, 500 (7th Cir. 2018) (non-precedential disposition) (*citing Feltmeier v. Feltmeier*, 798 N.E.2d 75, 85 (Ill. 2003)) (explaining that the continuing-violations doctrine was inapplicable because the plaintiff's injury ceased when his psychotic breakdown ended and he stopped taking the drugs at issue). In other words, even if Sandoz continued to mislead *other* consumers following Linda's death, as Lempa alleges, Sandoz did not continue to inflict injury on Lempa, and its actions, thus, do not constitute a continuing violation.

B. Federal Preemption

Sandoz next argues that Lempa's claims must be dismissed because they are "preempted under the Supreme Court's broad and sweeping decisions in *Bartlett* and *Mensing*." Mtn. Dismiss at 9. To the extent that Lempa's claims are premised on an argument that Sandoz's warnings or labeling (or both) were inadequate, Sandoz is correct. The Supreme Court has explained that generic drug manufacturers labor under a "duty of sameness," that requires "generic drug labels [to] be the same at all times as the corresponding brand-name drug labels." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); *see also Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 486 (2013). So "federal law preempts state tort laws when the generic drug manufacturer could not have abided by this duty without: (1) changing the drug's formula; (2) changing the drug's label; or (3) withdrawing the generic drug from the market altogether." *Wagner v. Teva Phars. USA, Inc.*, 840 F.3d 355, 358 (7th Cir. 2016). Here, there are at least some allegations in the Complaint that challenge the adequacy of Sandoz's labeling. *See* Compl. ¶¶ 30(a), 30(e), 37, 41-42. And, in relation to those allegations, there was no way for Sandoz to fulfill its duty to warn without changing the formula for the drug, changing the label, or to discontinue selling it. Any challenges to the adequacy of amiodarone's warning and labels are thus preempted.

Lempa points out in his response brief, though, that his claims are at least partly premised "on the defendants' violation of the FDCA's requirement to provide distributors with medication guides" and Sandoz's promotion of "amiodarone for off-label use." Pl.'s Resp. at 6-7. This distinguishes these claims from those brought in

Mensing and *Bartlett*. Sandoz counters that, even if this is true, Lempa's claims are still impliedly preempted because the duties to provide a Medication Guide and refrain from promoting off-label uses both arise under the Federal Food, Drug, and Cosmetic Act (FDCA). R. 31, Defs.' Reply at 7-8; *see* 21 C.F.R. § 208.24(b) (requiring drug manufacturers to make Medication Guides available for distribution to each patient with each prescription, by providing them—or the means to produce them—to distributors, packers, or authorized dispensers of the drug); 21 C.F.R. § 202.1(e)(6) (regulation under the FDCA prohibiting a drug manufacturer from promoting off-label uses of its prescription drugs). Relying on recent Sixth Circuit precedent, Sandoz argues that Lempa attempts "to privately enforce federal medication guide duties that only the federal government is permitted to enforce under 21 U.S.C. § 337(a)." *Id.* at 7 (citing *McDaniel v. Upsher-Smith Labs, Inc.*, 893 F.3d 941, 943 (6th Cir. 2018)). The Court disagrees.

Although state law claims that seek only to enforce FDA regulations are impliedly preempted, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001), Lempa does not literally bring claims for violations of the FDCA. He instead claims that Sandoz was negligent and violated its duty to warn Linda of the risks associated with amiodarone when it failed to provide a Medication Guide and promoted off-label uses. These are claims for violations of well-established state-law duties that predate the FDCA and do not necessarily depend on violations of the requirements imposed under the statute. Put another way, Lempa could bring his same claims—for failure to warn and negligence—even if the FDCA did not require

Medication Guides nor prohibit off-label promotion. But given that the statute *does* do those things, Lempa is allowed to introduce evidence about the indications for which the FDA approved amiodarone and the reasons it requires Medication Guides because those statutory requirements run parallel to Sandoz's state law duties. *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) ("The evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient.")[5]; *see also In re Testosterone Replacement Therapy Prod. Liab. Litig.*, 2017 WL 1836443, at *7 (N.D. Ill. May 8, 2017) ("In the present cases, plaintiffs' marketing claims are not impliedly preempted by the FDCA or under *Buckman*, because the claims are grounded in traditional state law principles of liability, such as negligence, failure to warn, strict product liability, and fraud that predate the relevant FDCA requirements."); *Gravitt v. Mentor Worldwide, LLC*, 289 F. Supp. 3d 877, 890 (N.D. Ill. 2018).

In sum, Lempa's claims survive preemption, but only to the extent that they rely on his allegations that Sandoz failed to provide a Medication Guide and promoted off-label uses of amiodarone. Lempa is not permitted to argue that Sandoz's labels were inadequate, because those claims are preempted under *Mensing* and *Bartlett*.

[5]Sandoz argues that *Bausch* is inapplicable here because it addressed the express preemption clause applicable to medical devices under the Medical Device Amendments to the FDCA. Defs.' Reply. at 9. Sandoz overlooks the heading in *Bausch* that states "implied preemption," as well as the court's statement that it was addressing implied preemption under *Buckman*. *Bausch*, 630 F.3d at 556.

C. Learned Intermediary Doctrine

Sandoz also challenges Lempa's claims under the learned intermediary doctrine, which states that prescription drug manufacturers have a duty to warn health-care professionals—but not the ultimate end-consumer—of the risks associated with its product. Mtn. Dismiss at 18 (citing *Hernandez v. Schering Corp.*, 958 N.E.2d 447, 452-53 (Ill. App. Ct. 2011)). The underlying basis for the doctrine "is that a doctor is considered in the best position to prescribe drugs and monitor their use because he is knowledgeable of the propensities of the drugs he is prescribing and the susceptibilities of his patient." *Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 784 (Ill. App. Ct. 2006) (citing *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 392 (Ill. 1987)). Lempa responds that Linda's doctor could not be considered a learned intermediary because Sandoz's warning was inadequate. Pl.'s Resp. at 8.

The Court agrees that there is, at least, a question of fact about Sandoz's warnings to Linda's doctor about off-label uses of amiodarone. Lempa alleges, among other things, that Sandoz "did not include warnings to prescribing physicians of amiodarone of the potential dangers associate with amiodarone toxicity and dangers to atrial fibrillation patients." Compl. ¶ 10. This precludes application of the learned intermediary doctrine at this stage of the litigation, because, under Illinois law, doctors are not considered learned intermediaries if they receive insufficient warnings. *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 43 (Ill. 2002) ("Doctors who have not been *sufficiently* warned of the harmful effects of a drug cannot be considered learned intermediaries and the adequacy of warnings is a question of fact,

not law, for the jury to determine.") (cleaned up) (emphasis in original). Moreover, Lempa correctly asserts that the learned intermediary doctrine is not typically applied at the dismissal-motion stage, because "[o]nly a physician or someone with specialized knowledge would be qualified to determine whether the warning was inadequate," meaning expert testimony is needed. *Hernandez*, 958 N.E.2d at 455-56 (cleaned up). Accordingly, the learned intermediary doctrine does not bar Lempa's claims at this stage.

D. Failure to State a Claim

Sandoz's lastly challenges Lempa's claims as insufficiently pled. Mtn. Dismiss at 15-20. Sandoz first takes issue with Lempa's off-label promotion and fraudulent concealment claims, which it argues do not meet the pleading standards for fraud under Rule 9(b). Mtn. Dismiss at 16-18 (citing Fed. R. Civ. P. 9(b)). The Court agrees with Sandoz as to Lempa's fraudulent concealment claims. To prove a claim of fraudulent concealment under Illinois law, a plaintiff must allege "that the defendant [engaged in the] concealment [of] a material fact when he was under a duty to disclose that fact to plaintiff." *Squires-Cannon v. Forest Pres. Dist. of Cook Cty.*, 897 F.3d 797, 805 (7th Cir. 2018) (cleaned up) (quoting *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584, 593 (Ill. 1996)). Rule 9(b) imposes a heightened pleading standard on claims of fraud—including fraudulent concealment—and requires plaintiffs to allege their claim with "particularity." *Squires-Cannon*, 897 F.3d at 805. The Seventh Circuit has interpreted this requirement as one "calling for the first paragraph of any

newspaper story"; a plaintiff must plead the who, what, when, where, and how. *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 569 (7th Cir. 2012).

Here, Lempa provides only broad, general allegations to support his claim that Sandoz fraudulently failed to disclose that amiodarone was approved by the FDA only as a drug of last resort. Compl. ¶¶ 40-41. He does not describe where and when these omissions occurred or who should have disclosed these material facts at what time. Lempa's fraudulent concealment allegations simply do not meet the requirements of Rule 9(b) as drafted.

Having said that, the Court is not convinced that Rule 9(b) precludes any of Lempa's other claims. Sandoz asserts that Lempa's off-label promotion allegations are subject to Rule 9(b), presumably because they sound in fraud. Defs.' Reply at 2. Assuming this is true, the Court agrees that Lempa's off-label promotion allegations do not meet the Rule 9(b) standard. But, it is far from clear, based on the Complaint, that Lempa intended his off-label promotion allegations to sound in fraud. The term "off-label" is mentioned four times in the Complaint, and is never accompanied by the terms "fraudulently," "knowingly," or "willingly." Compl. ¶¶ 9, 13, 30(b), 36. It is included in Lempa's section on failure to warn and negligence per se, but not his section on fraudulent concealment. And Lempa critically alleges that Sandoz engaged in "*negligent* promotional, marketing and sales efforts." Compl. ¶ 12 (emphasis added); *see also* Compl. ¶ 30(c). Lempa's "off-label" promotion allegations are thus not subject to Rule 9(b)'s heightened pleading standard, but rather Rule 8's notice pleading standard.

Under Rule 8, the remainder of Lempa's claims, which all sound in negligence, survive. In order to state a claim for negligence under Illinois law, "a plaintiff must plead a duty owed by a defendant to that plaintiff, a breach of duty, and injury proximately caused by the breach of duty." *Reynolds v. CB Sports Bar*, Inc., 623 F.3d 1143, 1148 (7th Cir. 2010) (cleaned up) (*quoting Bell v. Hutsell*, 931 N.E.2d 299, 302 (Ill. 2010)). When proceeding under a failure-to-warn theory, as Lempa does here, a plaintiff must show that the manufacturer failed to disclose an unreasonably dangerous propensity of the product known to the manufacturer, as to which the average consumer would not be aware. *Sollami v. Eaton*, 772 N.E.2d 215, 219 (Ill. 2002). And, under Illinois law, the doctrine of negligence per se "provides that where a cause of action does exist at common law, the standard of conduct to which a defendant will be held may be defined as that required by statute, rather than as the usual reasonable person standard." *Cuyler v. United States*, 362 F.3d 949, 952 (7th Cir. 2004) (cleaned up).

Lempa's allegations in the Complaint are sufficient to state a claim for failure to warn and negligence per se. He has alleged that Sandoz failed to disclose the risks associated with using amiodarone as a "first line" treatment for atrial fibrillation and failed to provide Medication Guides to distributors, pharmacists, physicians, and Linda, in violation of its duties under Illinois law. *See, e.g.*, Compl. ¶¶ 9, 30, 37. Lempa also alleges that Linda would not have taken amiodarone had she known the risks, *id.* ¶ 38, and, "[a]s a direct and proximate result of the defendants' respective negligence, Linda Lempa ingested the drug as instructed, and died," *id.* ¶ 31. Finally,

Lempa alleges that Sandoz breached FDA regulations when it negligently marketed amiodarone for an off-label use and failed to provide a Medication Guide. *Id.* ¶¶ 13, 15-16, 26-29, 30(c)-(d), 30(f), 36-37. This is enough for Lempa's negligence claims to survive dismissal.

Accordingly, only Lempa's fraudulent concealment claim is dismissed at this stage of the litigation. Because Lempa has not yet amended his Complaint in federal court, by April 22, 2019, he may have file an amended complaint repleading fraudulent concealment if he wishes to attempt to satisfy Rule 9(b) on that claim.[6]

IV. Conclusion

For the reasons discussed, the Defendants' motion to dismiss is granted as to Lempa's fraudulent concealment claim and any claims that rely on an argument that Sandoz's labeling was inadequate. It is denied as to the remainder of Lempa's claims. Lempa may have two weeks to file an amended complaint repleading his fraudulent concealment claim, this time with particularity.

ENTERED:

s/Edmond E. Chang
Honorable Edmond E. Chang
United States District Judge

DATE: March 29, 2019

[6]The Court strongly encourages Lempa to leave the contours of his other claims unchanged in order to avoid a second round of dismissal briefing over the same issues.