UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
AT LEXINGTON

TIMOTHY ROBINSON, on Behalf of T.R., a minor child,

Plaintiff,

V.

ELI LILLY AND COMPANY,

Defendant.

CIVIL ACTION
NO. 5:17-CV-338-KKC

OPINION AND ORDER

*** *** ***

This matter is before the Court pursuant to Defendant Eli Lilly's Motion to Dismiss for Failure to State a Claim (DE 10). For the following reasons, the motion is **GRANTED IN PART** and **DENIED IN PART**. The Court dismisses Robinson's claims[1] alleging design defects, manufacturing defects, breach of warranties, fraudulent concealment, and negligent misrepresentation. Robinson's failure to warn claims, arising in both strict liability and negligence, may proceed.

I. INTRODUCTION

In late 2000, during her first trimester of pregnancy, Gina Robinson took Prozac as prescribed by a physician. (DE 1-2 at 6). She later gave birth to T.R., who was born with cardiac birth defects, which required corrective surgery at the age of nine.

T.R.'s father, Timothy Robinson claims that at the time of Gina Robinson's pregnancy, the manufacturer and distributor of Prozac, Eli Lilly and Company, knew through animal

[1] The Court notes that these claims are brought by Timothy Robinson, on behalf of T.R., his minor child.

studies, post-marketing reports and other sources, that Prozac was associated with a significant risk of cardiac defects in babies whose mothers ingested Prozac during pregnancy. *Id.* at 8. Robinson claims that despite this knowledge, Eli Lilly aggressively and actively promoted Prozac "as being a safe alternative for pregnant women," and never informed doctors of the serious risks. *Id.* at 10. Robinson's complaint asserts multiple claims against Eli Lilly, including strict liability for failure to warn, negligence, breach of warranties, fraudulent concealment and negligent misrepresentation. Eli Lilly has moved to dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). (DE 10). Specifically, Eli Lilly argues that each of Robinson's claims are either preempted, fail to meet the pleading requirements, or are not viable claims under Kentucky law. The Court considers the arguments below.

II. ANALYSIS

A. Rule 12(b)(6)

In determining whether a plaintiff's complaint can withstand a motion to dismiss, the Court will assume the veracity of well-pleaded factual allegations and then determine whether they plausibly give rise to an entitlement to relief. *Ashcroft v. Iqbal,* 556 U.S. 662, 679, 129 S.Ct. 1937 (2009). A complaint should be dismissed pursuant to Rule 12(b)(6) if there is no law to support the claims, if the alleged facts are insufficient to state a claim, or if an insurmountable bar to relief exists on the face of the complaint. *See Browning v. Pennerton,* 633 F.Supp.2d 415, 429 (E.D. Ky. Jun. 22, 2009) (citing *Rauch v. Day & Night Mfg. Corp.,* 576 F.2d 697 (6th Cir. 1978).

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." *Moore v. Zydus Pharmaceuticals (USA), Inc.,* 277 F.Supp.3d 873, 877 (E.D. Ky. 2017) (quoting *Bishop v. Lucent Technologies, Inc.,* 520 F.3d 516, 519 (6th Cir. 2008)). "Even

under Rule 12(b)(6), a complaint containing a statement of facts that merely creates a *suspicion* of a legally cognizable right of action is insufficient." *Bishop,* 520 F.3d at 519.

1. Strict Liability in Tort – Failure to Warn

Robinson's first cause of action is styled as a failure to warn claim sounding in strict liability. (DE 1-2 at 20). To plead a failure to warn claim in a prescription drug case, the plaintiff must "allege facts for the Court to infer that (1) the manufacturer failed to provide her prescribing physician with adequate warnings about risks of which it knew or should have known and (2) the inadequate warnings proximately caused her injuries." *Estate of DeMoss v. Eli Lilly and Co.,* 234 F.Supp.3d 873, 880 (W.D. Ky. 2017). This test reflects that in 2004, Kentucky adopted the learned intermediary rule, an exception to the general rule that a drug manufacturer's duty to warn of any risks inherent in the product runs to the ultimate consumer. *See Larkin v. Pfizer, Inc.,* 153 S.W.3d 758, 770 (Ky. 2004). But "even though the manufacturer's duty to warn runs only to the learned intermediary, that warning must still be adequate." *Id.* at 764.

At this stage, Robinson has sufficiently alleged that the warnings provided by Eli Lilly were inadequate, and that they caused the relevant injury. In his complaint, Robinson adequately set out the specific means by which Eli Lilly knew or should have known of Prozac's alleged connection to cardiac birth defects. (DE 1-2 at 7) (citing animal studies, post-marketing reports, and other sources, including scholarly articles). Robinson alleges Eli Lilly failed to warn physicians or consumers of the risk of cardiac birth defects through labeling or any other means. *See, e.g.,* (DE 1-2 at 6-9). Robinson further claims that if Ms. Robinson's prescribing physicians or health care providers had known of this risk, she would have never started—or subsequently discontinued—her use of Prozac, and T.R. would not have suffered injury. (DE 1-2 at 12). At this stage of the litigation, the Court finds that

Robinson has stated a claim upon which relief may be granted. Therefore, Eli Lilly's motion to dismiss will be denied as to Robinson's first cause of action.

2. Negligence

Robinson also alleges that Eli Lilly was negligent in manufacturing, researching and designing Prozac. To prevail on a negligence claim under Kentucky law, a plaintiff must establish that:(1) the defendant owed a duty of care to the plaintiff; (2) the defendant breached its duty; and (3) there was consequent injury to the plaintiff. *See Mullins v. Commonwealth Life Ins. Co.,* 839 S.W.2d 245, 247 (Ky. 1992).

In his complaint, Robinson states that Eli Lilly was, among other things, negligent in manufacturing, researching, and designing Prozac; and that Eli Lilly failed to adequately test and warn of the risks and dangers of Prozac both before and after its sale. (DE 1-2 at 21). To the extent Robinson's negligence claim is based on a design defect, the claim is preempted by federal law as discussed in a subsequent section of this Opinion. To the extent Robinson alleges a negligent manufacturing claim, the claim must be dismissed. Robinson makes no factual allegations as to how Eli Lilly might have breached the duty of care in manufacturing Prozac or deviated from Prozac's intended design. *See Greene v. B.F. Goodrich Avionics Systems, Inc.,* 409 F.3d 784, 788 (6th Cir. 2005) ("Under Kentucky law, a manufacturing defect exists in a product when it leaves the hands of the manufacturer in a defective condition because it was not manufactured or assembled in accordance with its specifications").

As previously discussed, Robinson has sufficiently claimed that Lilly failed to warn of potential risks regarding the usage of Prozac during pregnancy. This does not, however, prevent Robinson from asserting his strict liability claim. *See generally Estate of DeMoss,* 234 F.Supp.3d at 881 (W.D. Ky. 2017) ("Under Kentucky law, a plaintiff can advance both a

strict-liability claim and a negligence claim against the manufacturer of a product for injury suffered by that product") (internal citation omitted).

3. Breach of Warranty

The third and fourth causes of action are breach of warranty claims: express and implied. (DE 1-2 at 22). Neither claim survives the motion to dismiss.

To begin, the Court questions whether an express warranty claim can be premised on an omission, such as Eli Lilly's failure to warn of a particular risk. *See Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378, 395 (6th Cir. 2013) (finding no merit to express-warranty claims under Tennessee law where plaintiff attacked adequacy of drug label, rather than a false affirmation); *see also House v. Bristol-Myers Squibb Company*, No. 3:15-CGV-00894-JHM, 2017 WL 55876 (W.D. Ky. Jan. 4, 2017) (finding plaintiff could not base express warranty on an omission, such as failure of prescribing information to contain adequate information, under Kentucky law).

Regardless, claims for breach of warranty under Kentucky law may proceed only where there is privity between the parties. *See Waterfill v. National Molding Corp.*, 215 Fed.Appx. 402, 405 (6th Cir. 2007); *see also Naiser v. Unilever U.S., Inc.*, 975 F.Supp.2d 727, 738 (W.D. Ky. 2013). Contractual privity must be uninterrupted and direct from the seller to "his buyer." *See Compex Intern. Co., Ltd. V. Taylor*, 209 S.W.3d 462, 465 (2006) (citing KRS 355.2-318). Here, Robinson doesn't allege any kind of contractual privity between Lily and the consumer. As such, the claim for implied breach of warranty is dismissed. *See Munn v. Pr Hosp. Products Group, Inc.*, 750 F.Supp.244, 248 (W.D. Ky. 1990) (dismissing an implied warranty claim because the doctor, and not the patient, purchased surgically implanted nails).

Robinson argues an exception to privity exists for his express warranty claim. (DE 14 at 8). A line of cases in the United States District Court for the Western District of Kentucky

has recognized that Kentucky law allows an exception to the privity requirement when a manufacturer makes express warranties directly to the intended consumer of the product. *See e.g., Bosch v. Bayer Healthcare Pharm., Inc.,* 13 F.Supp.3d 730, 746-49 (W.D. Ky. 2014); *see also Huff v. Howmedica Osteonics,* No. 5:14-CV-00134-TBR, 2014 WL 4918807 (W.D. Ky. Sept. 30, 2014). But unlike in *Bosch* and *Huff*, the complaint in this case does not specify the warranties allegedly made by Eli Lilly. *See e.g., Bosch,* 13 F.Supp.3d at 746-49 (noting that the complaint identified the types and sources of communication, when plaintiff received the communications, and the specific assertions contained within); *see also Huff,* No. 5:14-CV-00134-TBR, 2014 WL 4918807 (noting that the Defendant did not dispute making express warranties to Plaintiff through the media about the effectiveness and safety of the product).

In the section of his complaint alleging breach of an express warranty, Robinson cites a litany of entities to which Eli Lilly supposedly made express warranties, but fails to point to even one specific communication directed to the consumer of the product—and certainly not one in which Lilly represented that Prozac was safe for, or intended to be used during, pregnancy. *See* (DE 1-2 at 22-23). Elsewhere in his complaint, Robinson alleges that Eli Lilly misrepresented to the public that Prozac was safe to take during pregnancy.[2] But Robinson again fails to provide the Court with any level of detail, leaving the Court to speculate as to when, where, how, and by whom the statements were made. Such speculation is not sufficient to describe an express warranty, much less one that specifically ran to the ultimate consumer, and therefore Robinson cannot avail himself of the privity exception. Accordingly, Robinson's express warranty claim is dismissed without prejudice.

4. Fraudulent Concealment

[2] Robinson alleges that Eli Lilly "touted Prozac as being a safe alternative for pregnant women," and "misrepresented and continue[s] to misrepresent to the public...that the drug is safe to take during pregnancy." (DE 1-2 at 10-11).

Robinson alleges that Eli Lilly fraudulently concealed from others its knowledge concerning the risk of taking Prozac while pregnant, including concealment from Ms. Robinson, her prescribing physicians, and the FDA. (DE 1-2 at 23). To the extent that Robinson asserts a claim of fraud on the FDA, it is preempted and dismissed. *See Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 121 S.Ct. 1012 (2001); *see also Garcia v. Wyeth-Ayerst Labs,* 385 F.3d 961, 966 (6th Cir. 2004) ("*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims").

The remaining portion of Robinson's claim does not meet the applicable pleading requirement. The Sixth Circuit has explained that a claim based in fraud, including fraud by omission, is subject to a heightened pleading requirement under the Federal Rules of Civil Procedure:

> Rule 9(b) is designed, not only to put defendants on notice of alleged misconduct, but also to prevent fishing expeditions...and to narrow potentially wide-ranging discovery to relevant matters. To maintain its fraud-by-omission claim under this standard, [plaintiff] must specify the who, what, when, where and how of the alleged omission. Specifically, it must plead: (1) precisely what was omitted; (2) who should have made a representation; (3) the content of the alleged omission and the manner in which the omission was misleading; and (4) what [defendants] obtained as a consequence of the alleged fraud.

Republic Bank & Tr. Co. v. Bear Stearns & Co., Inc., 683 F.3d 239, 255-56 (6th Cir. 2012); *see also House v. Bristol-Myers Squibb Company,* No. 3:15-CGV-00894-JHM, 2017 WL 55876 (W.D. Ky. Jan. 4, 2017) (dismissing Kentucky fraudulent concealment claim against drug manufacturers where plaintiff failed to allege sufficient facts under Rule 9(b)).

In this case, Robinson alleges that Eli Lilly, "[a]t all times relevant hereto...conducted a sales and marketing campaign to promote the sale of Prozac and willfully deceive" a generically broad cast of characters, including "Ms. Robinson and her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare

communities, the FDA, and the public in general." (DE 1-2 at 23-24). Robinson alleges that the timeframe of Eli Lilly's fraudulent concealment is "from the time Prozac was first tested...up to the present," an expansive period that presumably begins prior to Ms. Robinson's alleged purchase and use of Prozac in 2000. (DE 1-2 at 23). The extent of Robinson's specificity is that the concealment was done through "false, fraudulent and misleading advertising, marketing messages, publications and all such public statements" issued by Eli Lilly. *Id.* at 24. Notably, Robinson does not cite the Court to a single document or statement during the—at minimum—eighteen-year period in which he alleges omissions occurred that makes plausible what he claims. Robinson discusses the alleged practices "only at a high level of generality," and the Court simply cannot find that such discussion meets the heightened pleading requirements. *Republic Bank,* 683 F.3d at 256. As such, Robinson's claim for fraudulent concealment is dismissed without prejudice.

5. Negligent Misrepresentation

Robinson's sixth cause of action alleges that Eli Lilly made negligent misrepresentations regarding Prozac and its use during pregnancy. (DE 1-2 at 26). The Sixth Circuit has indicated that, under Kentucky law, negligent misrepresentation claims are also subject to Rule 9(b)'s heightened pleading requirements. *See Republic Bank,* 683 F.3d at 247. Rule 9(b) "requires a plaintiff: (1) to specify the allegedly fraudulent statements; (2) to identify the speaker; (3) to plead when and where the statements were made; and (4) to explain what made the statements fraudulent." *Id.*

Robinson's negligent misrepresentation claim alleges the same broad time frame as his fraudulent concealment claim (DE 1-2 at 26); both claims involve the same sweeping cast of characters allegedly targeted by Eli Lilly (DE 1-2 at 27); and Robinson's negligent misrepresentation claim, similar to his fraudulent concealment claim, alleges misrepresentations at only a high level of generality. (DE 1-2 at 27) ("These

misrepresentations were made directly by Defendant, by sales representatives, detail persons and other authorized agents of said Defendant, and in publications and other written materials....."). Again, Robinson's complaint fails to identify any specific statement by Eli Lilly that makes plausible the allegation that a misrepresentation was contained therein. For the same reasons as his fraudulent concealment claim, Robinson's negligent misrepresentation claim does not meet the heightened pleading requirements, and must be dismissed without prejudice.

B. Preemption

Eli Lilly argues that Robinson's design defect and failure to warn claims, sounding in strict liability and negligence, are preempted by federal law—specifically through regulations enforced by the Food and Drug Administration ("FDA"). Eli Lilly asserts that both claims are preempted by the impossibility doctrine. (DE 10 at 3).

It is a fundamental principle of the Constitution that Congress has the power to preempt state law. *See Crosby v. National Foreign Trade Council,* 530 U.S. 363, 372, 120 S.Ct. 2288 (2000). Congress can preempt state law either expressly or impliedly:

> Express preemption applies where Congress, through a statute's express language, declares its intent to displace state law. Where a court deems express preemption inapplicable, it may still find implied preemption when federal and state laws conflict. So-called "conflict preemption" takes two forms: (i) impossibility preemption, where it is impossible for a private party to comply with both state and federal law, and (ii) obstacle preemption, where the state law is an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Robbins v. New Cingular Wireless PCS, LLC, 854 F.3d 315, 319 (6th Cir. 2017) (internal citations omitted). Generally, plaintiffs who are injured by brand-name prescription drugs retain state-law tort remedies against the manufacturer, "provided it is not impossible for the drug manufacturer to comply with both state and federal law." *Yates v. Ortho-McNeil-Janssen Pharm., Inc.,* 808 F.3d 281, 294 (6th Cir. 2015). The Supreme Court has stated that, "[t]he question for impossibility is whether the private

party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing,* 564 U.S. 604, 620, 131 S.Ct. 2567 (2011). Neither party currently contests that Eli Lilly is a brand-name manufacturer for purposes of FDA regulations.

1. Failure to Warn Claims

At this point in the litigation, Robinson's failure to warn claims are not preempted. Previously, the Supreme Court has indicated that manufacturers of brand-name pharmaceuticals bear the responsibility for the contents of a drug's label at all times—the manufacturer is charged with both crafting an adequate label and ensuring that its label is adequate as long as the drug remains on the market. *See Wyeth v. Levine,* 555 U.S. 555, 570-71, 129 S.Ct. 1187 (2009). The Sixth Circuit has previously explained *Wyeth*:

> In a 2009 opinion authored by Justice Stevens, the Supreme Court held that failure-to-warn claims against branded-drug manufacturers were not preempted by federal law, because 1) it is not impossible for [a branded-drug manufacturer] to comply with its state and federal law obligations and 2) state common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA. In finding no impossibility preemption, the Court found that because the changes being effected (CBE) process allowed branded-drug manufacturers to strengthen warnings without prior approval of the FDA, compliance with both federal and state duties was not impossible. The Court did not find it significant that the FDA has authority to reject unilateral labeling changes made pursuant to the CBE process, finding it difficult to accept that the FDA would not have permitted a change to a stronger warning. Without clear evidence that the FDA would not have approved a change, the Court was unwilling to find impossibility.

Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 582 (6th Cir. 2013) (internal citations and quotations omitted). Here, Robinson claims that Eli Lilly should have strengthened Prozac's label to include a more adequate warning regarding the risks associated with using the drug while pregnant. The Court has already concluded that Robinson has provided sufficient allegations to state a claim for failure to warn. At this early stage of litigation, the Court is faced with no "clear evidence" that the FDA would have denied such a change to Prozac's labeling, and the Court finds that Robinson's failure to warn claims are not preempted. *See e.g., Wyeth* 555 U.S. 555, 570-71, 129 S.Ct. 1187.

2. Design Defect Claims

In Robinson's second cause of action, he claims Eli Lilly breached a duty in that it negligently and carelessly manufactured, designed, formulated, produced and prepared Prozac. (DE 1-2 at 21). Eli Lilly alleges that these "design defect" claims are preempted by federal law and should be dismissed. The Court agrees.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), drug manufacturers must gain approval from the FDA before introducing a new drug into interstate commerce. 21 U.S.C. § 355(a). And in contrast to the manufacturer's unilateral ability to strengthen a drug's label discussed above, once a drug is approved, "the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Mutual Pharmaceutical Co., Inc. v. Bartlett,* 570 U.S. 472, 477 133 S.Ct. 2466 (2013) (quoting 21 C.F.R. § 314.70(b)(2)(i)).

Here, Robinson's complaint does not cite a single change to Prozac's design that was required by Kentucky law—at most, Robinson alleges that it is the chemical make-up of Prozac that created the risk suffered by T.R. *See* (DE 1-2 at 7) (citing the dangers of fluoxetine and Prozac's effect on serotonin levels, "the primary human substance affected by Prozac"). Even assuming Kentucky law required a change regarding the make-up of Prozac, the federal law discussed above makes it clear that Eli Lilly could not have independently made such fundamental changes to Prozac's formula. Thus, Robinson's design defect claims are preempted. *See PLIVA, Inc.,* 564 U.S. 604, 624, 131 S.Ct. 2567 ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes"); *see also Yates,* 808 F.3d

at 297-299 (finding a state law claim that manufacturer should have changed dosage level of an active ingredient after FDA approval to be "clearly preempted").

To the extent that Robinson attempts to ground his claim in a pre-approval duty, the claim is still preempted. *See Yates*, 808 F.3d at 300 ("Defendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing [the drug], and certainly prior to [Plaintiff's] use of the drug"); *see also Fleming v. Janssen Pharmaceuticals, Inc.*, 186 F.Supp.3d 826 (W.D. Tn. 2016) (finding design defect claims premised on Defendant's duty to design drug differently prior to FDA approval to be preempted). Accordingly, Eli Lilly's motion to dismiss is granted as to Robinson's design defect claims.

C. Request For Leave to Amend

In his response to Eli Lilly's motion to dismiss, Robinson has also included a request for leave to amend his complaint if the Court were to find that portions were "improperly pled or insufficient in some respect." (DE 14 at 13). The Court does not consider this an appropriate motion to amend. *See DeMoss,* 234 F.Supp.3d at 885. If Robinson wants the Court to consider such a request, he should submit a properly supported motion, with a copy of the amended complaint attached, no later than twenty-one (21) days from the entry of the Memorandum Opinion and Order. Thereafter, Eli Lilly may file its response, and the Court will address the merits of Robinson's motion.

III. CONCLUSION

Accordingly, and being otherwise sufficiently advised, the Court **HEREBY ORDERS** that:

(1) Defendant Eli Lilly's Motion to Dismiss (DE 10) is **DENIED** as to Robinson's failure to warn claim arising in strict liability;

(2) Defendant Eli Lilly's Motion to Dismiss (DE 10) is **DENIED** as to Robinson's failure to warn claim arising in negligence;

(3) Defendant Eli Lilly's Motion to Dismiss (DE 10) is **GRANTED** as to all other claims; and

(4) Plaintiff Robinson shall submit its motion and amended complaint no later than twenty-one (21) days from the entry of this Memorandum Opinion and Order.

It is so **ORDERED**.

Dated August 23, 2018.

Signed By:
Karen K. Caldwell
United States District Judge