UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

TANYA WARREN, LARRY WARREN, Plaintiffs, vs. BOEHRINGER INGLEHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, ELI LILLY AND COMPANY, LILLY USA, LLC, Defendants.	)	No. 1:16-cv-01326-SEB-DML

MEMORANDUM ORDER

Spouses Tanya and Larry Warren ("Tanya," "Larry," together, "the Warrens") brought this products-liability action based on diversity jurisdiction against the manufacturers of Jardiance, a drug for treating diabetes: Boehringer Ingelheim Pharmaceuticals, Inc., and its parent company Boehringer Ingelheim International GmbH ("Boehringer"), and Lilly USA, L.L.C., and its parent company Eli Lilly and Company ("Lilly") (together, "the Manufacturers").

Before the Court are two motions to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). The Manufacturers jointly seek dismissal of all the Warrens' claims as insufficiently pleaded under Federal Rules of Civil Procedure 8 and 9, and of one claim as pre-empted by federal law ("the Manufacturers' motion").

Lilly separately seeks dismissal of two of the Warrens' claims as pre-empted by federal law for a reason peculiar to it ("Lilly's motion").

The Manufacturers' motion is granted in part and denied in part. Lilly's separate dismissal motion is granted in its entirety.

Factual and Procedural History

Taken as true, the Warrens' factual allegations reveal the following: The Warrens are Louisiana citizens who live in the town of Olla, Louisiana. Pls.' Am. Compl. ¶¶ 9–10. Tanya suffers from type 2 diabetes mellitus, *id.* at ¶ 21, for which her endocrinologist prescribed Jardiance, at a dosage of 10 milligrams taken by mouth once daily, beginning on or about February 4, 2015. *Id.* at ¶¶ 45–46.

Jardiance is indicated "for the improvement of glycemic control in adults with type 2 diabetes." *Id.* at ¶ 26. It belongs to a class of drugs called sodium glucose cotransporter 2 (SGLT2) inhibitors, *id.* at ¶ 22, the effect of which is to "inhibit renal glucose reabsorption through the SGLT2 receptor in the proximal renal tubules, causing glucose to be excreted through the urinary tract . . . ." *Id.* at ¶ 23. SGLT2 inhibitors "are designed to target primarily the SGLT2 receptor, but have varying selectivity for this receptor, and block other sodium-glucose cotransporter receptors, including SGLT1." *Id.* at ¶ 24.

After Jardiance's release to market,[1] the United States Food and Drug Administration (FDA) received reports that some of its users experienced diabetic

[1] The Warrens do not allege a date when Jardiance was released.

ketoacidosis. *Id.* at ¶ 30. Ketoacidosis is a "life-threatening" condition, *id.* at ¶ 5, that "may lead to complications such as cerebral edema, pulmonary edema, cerebrovascular accident, myocardial infarction, nonspecific myocardial injury, severe dehydration, and coma." *Id.* at ¶ 36. Jardiance may also make ketoacidosis more difficult to detect "because in many cases Jardiance will keep blood sugar below 250 mg/dl, a threshold often used when diagnosing diabetic ketoacidosis." *Id.* at ¶ 37. In December 2015, the FDA requested that the Manufacturers of Jardiance and the manufacturers of other SGLT2 inhibitors warn their users about the risks of ketoacidosis. *Id.* at ¶ 32. The Manufacturers apparently declined the FDA's request. *See id.* at ¶¶ 39–41, 131(a), (b).

Tanya began taking Jardiance as directed by her endocrinologist. *Id.* at ¶ 45. On May 28, 2015, less than four months after it was prescribed for her, Tanya was hospitalized for ketoacidosis. *Id.* at ¶ 47. The Warrens note that Jardiance and other SGLT2 inhibitors may also cause kidney and bone problems in their users, *e.g.*, *id.* at ¶ 23, 31, 34–35, 38–39, 43, 135, but Tanya does not claim to have suffered such conditions. However, as a result of ketoacidosis, Tanya, and derivatively Larry, experienced "pain and suffering, emotional distress, loss of enjoyment of life, and economic loss[.]" *Id.* at ¶ 48.

The Warrens brought the instant action in this Court on May 27, 2016. Dkt. 1. In response to our order, Dkt. 4, the Warrens filed an amended complaint properly setting out their diversity jurisdiction allegations on June 9, 2016. Dkt. 5. The amended complaint alleges eleven claims against all the Manufacturers, whom the Warrens hold

jointly responsible for all aspects of Jardiance's design and marketing. Pls.' Am. Compl. ¶ 27.

The Warrens seek to hold the Manufacturers liable as follows: Counts (I) defective design; (II) failure to warn; (III) negligence; (IV) negligent misrepresentation; (V) breach of implied warranty of merchantability; (VI) breach of express warranty; (VII) fraudulent misrepresentation; (VIII) fraudulent concealment; (IX) deceptive acts under Indiana's Deceptive Consumer Sales Act, Ind. Code ch. 24-5-0.5; (X) Terry's loss of consortium; and (XI) punitive damages. The Manufacturers moved to dismiss the amended complaint on September 20, 2016. Dkt. 20. Lilly separately moved to dismiss two of the claims that same day. Dkt. 22. Each motion has been fully briefed and is now ripe for decision. Dkt. 21, 23, 26–28, 30.

Legal Standard

"A pleading that states a claim to relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief . . . ." Fed. R. Civ. P. 8(a); *Adams v. City of Indianapolis*, 742 F.3d 720, 728 (7th Cir. 2014). A motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) "test[s] the legal sufficiency of a complaint." *Triad Assocs., Inc. v. Chi. Hous. Auth.*, 892 F.2d 583, 586 (7th Cir. 1989), *abrogated on other grounds by Bd. of Cty. Comm'rs v. Umbehr*, 518 U.S. 668 (1996). To survive dismissal,

> a complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). 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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). . . . We draw all reasonable inferences and facts in favor of the nonmovant, but need not accept as true any legal assertions. *Vesely v. Armslist LLC*, 762 F.3d 661, 664–65 (7th Cir. 2014).

Wagner v. Teva Pharms. USA, Inc., 840 F.3d 355, 357–58 (7th Cir. 2016). This Court has previously noted that, "[a]lthough *Twombly* and *Iqbal* represent a new gloss on the standards governing the sufficiency of pleadings, they do not overturn the fundamental principle of liberality embodied in Rule 8." *DuRocher v. Riddell, Inc.*, 97 F. Supp. 3d 1006, 1013 (S.D. Ind. 2015) (Barker, J.).

Where, as here, the deadline for amending a complaint as of right has passed, Fed. R. Civ. P. 15(a)(1)(B), further amendment requires leave of court or the defendants' consent. *Id.* at (a)(2). "Although leave to file a second amended complaint should be granted liberally, a district court may deny leave for several reasons including . . . futility of amendment." *Dubicz v. Commonwealth Edison Co.*, 377 F.3d 787, 792 (7th Cir. 2004) (quotations omitted); *see* Fed. R. Civ. P. 15(a)(2) ("The court should freely give leave when justice so requires.").

Analysis and Decision

We turn first to resolve a choice of law issue. Thereafter, we address whether the Warrens' complaint satisfies Rule 8, Fed. R. Civ. P., by advancing plausible claims to relief. Assuming the allegedly pre-empted claims satisfy Rule 8, we finally will take up the pre-emption defenses raised jointly by the Manufacturers and separately by Lilly.

I. Choice of Law

A federal court sitting in diversity applies the whole law of the state in which it sits, that is, its substantive law including its choice-of-law rules. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941); *Auto-Owners Ins. Co. v. Websolv Computing, Inc.*, 580 F.3d 543, 547 (7th Cir. 2009). A federal court's task is to apply the law "as we believe the highest court of the state would apply it." *Pisciotta v. Old Nat'l Bancorp*, 499 F.3d 629, 634 (7th Cir. 2007).

The Manufacturers contend that Indiana courts would apply Louisiana law in resolving this case. The Warrens tacitly concede that point by failing to contest it, by defending the sufficiency of their complaint under Louisiana law, and by conceding that Louisiana law bars several of their claims. *See* Pls.' Resp. Br., pp. 4–9, 9 n. 3. Because a court "do[es] not worry about conflict of laws unless the parties disagree on which state's law applies[,]" *Wood v. Mid-Valley, Inc.*, 942 F.2d 425, 427 (7th Cir. 1991) (distinguishing subject-matter jurisdiction and federal comity), we shall apply Louisiana law to this case without further discussion.

Accordingly, the Manufacturers' motion is GRANTED as to the Warrens' Count (IX) deceptive acts brought under Indiana's Deceptive Consumer Sales Act, Ind. Code ch. 24-5-0.5. Because amendment would be futile, Count (IX) is DISMISSED WITH PREJUDICE.

II. The Warrens' Claims Under Louisiana Law

In Louisiana, "the *exclusive* theories of liability for manufacturers for damage caused by their products" are established by the Louisiana Products Liability Act (LPLA). La. Stat. Ann. § 9:2800.52 (emphasis added); *Reynolds v. Bordelon*, 2014-2371

(La. 6/30/15); 172 So. 3d 607, 612. A plaintiff may not recover for damage caused by a manufacturer's product "on the basis of any theory not set forth" in the LPLA. La. Stat. Ann. § 9:2800.52; *Ashley v. Gen. Motors Corp.*, 27,851 (La. App. 2 Cir. 1/24/96); 666 So. 2d 1320, 1321–22.

The Warrens concede that "the LPLA's exclusivity provision bars . . . claims beyond [its] scope . . . ." Pls.' Resp. Br., p. 9 n.3. This concession is well taken. It reaches Counts (III) negligence, *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 261 (5th Cir. 2002); (IV) negligent misrepresentation, *Donald v. AstraZeneca Pharms., L.P.*, No. 16-17753, 2017 WL 1079186 (E.D. La. Mar. 22, 2017); (V) breach of implied warranty of merchantability, *Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1251 (5th Cir. 1997); (VII) fraudulent misrepresentation, *id.*; and (VIII) fraudulent concealment, *Grenier v. Medical Engineering Corp.*, 99 F. Supp. 2d 759, 763 (W.D. La. 2000). Count (XI) punitive damages is generally unavailable under Louisiana law unless expressly authorized by statute, *Int'l Harvester Credit Corp. v. Seale*, 518 So. 2d 1039, 1041 (La. 1988), and the LPLA contains no such authorization. *See* La. Stat. Ann. §§ 2800.51 through .60; *see also, e.g., Bladen v. C.B. Fleet Holding Co.*, 487 F. Supp. 2d 759, 770 (W.D. La. 2007).

The Manufacturers' motion is therefore GRANTED as to each of these claims. With the dismissal of the fraud claims, the Manufacturers' Rule 9, Fed. R. Civ. P., arguments are moot. *See* Fed. R. Civ. P. 9(b) (fraud pleaded with particularity); Dkt. 20 (moving to dismiss under Rule 9(b)). Because amendment would be futile, Counts (III), (IV), (V), (VII), (VIII), and (XI) are DISMISSED WITH PREJUDICE.

The Manufacturers argue further that "the Court should dismiss *all* of [the Warrens'] substantive claims, because [the Warrens] have not brought any of these claims pursuant to the LPLA." Defs.' Br. Supp., p. 8 (emphasis added). With this, we disagree. "[A] plaintiff need not plead legal theories in her complaint[,]" *King v. Kramer*, 763 F.3d 635, 642 (7th Cir. 2014), and "specifying an incorrect theory is not a fatal error." *Rabe v. United Air Lines, Inc.*, 636 F.3d 866, 872 (7th Cir. 2011).

The question remaining, then, is whether the Warrens have pleaded sufficient facts to raise a facially plausible claim to relief under the LPLA. *Wagner*, 840 F.3d at 358. The Warrens argue that their four remaining claims are sufficiently pleaded under the LPLA to survive dismissal: Counts (I) defective design, (II) failure to warn, (VI) breach of express warranty, and Terry's derivative claim for Count (X) loss of consortium. We discuss these claims below.

Under the LPLA, the manufacturer of a product is liable for damage proximately caused "by a characteristic of the product that renders the product unreasonably dangerous" arising from "a reasonably anticipated use of the product" by the plaintiff or another. La. Stat. Ann. § 9:2800.54(A); *Reynolds*, 172 So. 3d at 612. Thus, a plaintiff under the LPLA must prove four elements:

> (1) that the defendant is a manufacturer of the product; (2) that the [plaintiff's] damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous"; and (4) that the [plaintiff's] damage arose from a reasonably anticipated use of the product by the product by the [plaintiff] or someone else.

Stahl, 283 F.3d at 261.

A product may be found unreasonably dangerous in only four respects: in construction or composition;[2] in design; in failing to provide an adequate warning; and in failing to conform to an express warranty of the manufacturer. La. Stat. Ann. § 9:2800.54(B)(1) through (4); *Reynolds*, 172 So. 3d at 612–13. As relevant here, the characteristic allegedly making the product unreasonably dangerous "must exist at the time product left the control of its manufacturer." La. Stat. Ann. § 9:2800.54(C); *Reynolds*, 172 So. 3d at 613.

The Warrens allege that the Manufacturers manufactured Jardiance, Pls.' Am. Compl. ¶ 27, and that the Manufacturers "expected and intended Jardiance to reach, and it did in fact reach, [Tanya] without any substantial change in the condition of the product from when it was initially manufactured . . . ." *Id.* at ¶ 68.The Warrens allege further that Jardiance is prescribed for the treatment of adult type 2 diabetes, *id.* at ¶ 26, that Tanya has type 2 diabetes, *id.* at ¶ 29, and that Tanya was prescribed Jardiance by her endocrinologist and took it as directed. *Id.* at ¶ 45. Finally, the Warrens allege that, as a

[2] "[A] product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." *Reynolds*, 172 So. 3d at 613 (citing La. Stat. Ann. § 9:2800.55). The Warrens have not pleaded a freestanding claim for defective construction. The Manufacturers point out that, under Count (I) defective *design*, the Warrens allege in conclusory fashion that the Manufacturers "manufactured . . . Jardiance . . . in a defective and unreasonably dangerous condition," Pls.' Am. Compl. ¶ 58, and the Warrens fleetingly argue that their complaint "support[s] a reasonable inference that [Jardiance] was . . . improperly constructed or composed." Pls.' Resp. Br., p. 6. We disagree. Outside the above-quoted Paragraph 58, no allegation, conclusory or otherwise, appears in the complaint as might raise and support a defective construction claim. To the extent the Warrens have attempted to raise a defective construction claim, it is insufficiently pleaded and hereby dismissed without prejudice.

result, Tanya suffered ketoacidosis and its "severe and life threatening side effects . . . ." *Id.* at ¶ 21. These averments plausibly allege that the Manufacturers are manufacturers of the product, that any unreasonable danger existed at the time the product left the Manufacturers' control, and that Tanya's damage arose from a reasonably anticipated use of the product by her.

We examine next each ground of unreasonable danger asserted and its causal relationship to the Warrens' injuries.

A. Count (I): Defective Design

The Warrens plead first that Jardiance is unreasonably dangerous in design. Under the LPLA,

> A product is unreasonably dangerous in design if, at the time the product has left its manufacturer's control:
>
> (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and
>
> (2) The likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

Reynolds, 172 So. 3d at 614 (quoting La. Stat. Ann. § 9:2800.56).

The Manufacturers argue that the Warrens failed to plead, as required, "a specific alternative design . . . ." Defs.' Br. Supp., p. 10; *see Theriot v. Danek Medical, Inc.*, 168 F.3d 253, 255–56 (5th Cir. 1999) (affirming summary judgment for defendant under LPLA where plaintiff did not present evidence of alternative design); *Reynolds*, 172 So.

3d at 614 (affirming summary judgment for defendant where "plaintiff proposed no other design for the product" and "admitted that he did not develop an alternative design"). The Manufacturers argue further that the Warrens have not sufficiently pleaded that the risk-utility balance would weigh in their favor, Defs' Br. Supp., p. 12, nor a specific causal relationship between the alleged defects and Tanya's injuries. *Id.* at 12–13.

If put to their proof, the Warrens will be required to show the existence, not merely of alternative therapies for diabetes, but of an alternative design for Jardiance. *See Theriot*, 168 F.3d at 255. Thus, even if proved, the Warrens' allegation that there are "several alternative[] safer methods for treating diabetes [than Jardiance], including diet and exercise and other anti-diabetic agents[,]" Pls.' Am. Compl. ¶ 44, will not entitle them to relief. The question before us, however, is not whether the Warrens have alleged a *prima facie* case, but whether the Warrens have "'raise[d] a reasonable expectation that discovery will reveal evidence' to support liability for the wrongdoing alleged." *Adams*, 742 F.3d at 729 (quoting *Twombly*, 550 U.S. at 556).[3]

The Warrens allege that "adverse event reporting" shows "an increased rate of reports for ketoacidosis in people taking Jardiance compared to other glucose-lowering medications." Pls.' Am. Compl. ¶ 35(j). The Warrens allege further that Jardiance is particularly unsuitable for a class of patients "whose ketones increase," *id.* at ¶ 64; *see*

[3] We note that, except for general pleading principles as set out under "Legal Standard" above, both parties rely entirely or nearly so on Fifth Circuit authority for their plausibility arguments. While courts within the Fifth Circuit are more accustomed to applying the LPLA than courts within the Seventh Circuit, our court nevertheless is bound by Seventh, not Fifth, Circuit pleading standards.

also id. at ¶ 35(b), (f); that Jardiance-induced ketoacidosis "may lead to delayed treatment because in many cases Jardiance will keep blood sugar below 250 mg/dl, a threshold often used when diagnosing diabetic ketoacidosis[,]" *id.* at ¶ 37; and that "SGLT2 inhibitors . . . have varying selectivity for [the SGLT2] receptor, and block other sodium-glucose cotransporter receptors, including SGLT1." *Id.* at ¶ 24; *see also id.* at ¶ 35(a), (c). The Warrens allege finally that "[t]here were practical and technically feasible alternative[s]" available to the Manufacturers, "including . . . developing a[n] SGLT2 inhibitor with a different safety profile[,]" that would not have "reduced the utility of Jardiance" or "cost substantially more to develop[.]" *Id.* at ¶ 63.

The Warrens have alleged, or raised reasonable inferences of, respects in which Jardiance is plausibly defective: by increasing the risk of ketoacidosis as compared to other drugs of its class; by particularly increasing the risk of ketoacidosis in a population vulnerable to "ketone[] increase," *id.* ¶ 64; by keeping blood glucose beneath a certain diagnostic threshold, tending to increase the harm of ketoacidosis when it occurs; and by selecting for the SGLT2 receptor with lower accuracy than other SGLT2 inhibitors. The Warrens allege that Jardiance could be freed of these defects while still remaining a viable, cost-effective SGLT2 inhibitor or other glucose-lowering medication. These allegations are sufficient to withstand dismissal. *See Garner v. Boehringer Ingelheim Pharms., Inc.*, 888 F. Supp. 2d 911, 924–25 (S.D. Ill. 2012) (denying motion to dismiss under Illinois law where plaintiff alleged drug's increased risk of harm as against others in class, increased difficulty of diagnosis of harm, and increased danger to specific population of patients). Rule 8 does not require that the Warrens come to court armed

with pharmacologically rigorous design specifications or accounts of mechanisms of action. "[A] plaintiff's pleading burden should be commensurate with the amount of information available to them." *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010) (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1212 (8th Cir. 2010) (Melloy, J., dissenting)).

The Warrens' allegations would be stronger and clearer, however, if they included a personalized causal connection between the above-recited allegations and Tanya's ketoacidosis: for example, that diagnosis of Tanya's ketoacidosis was unusually delayed, or that Tanya is particularly vulnerable to "ketone[] increase[.]" Pls.' Am. Compl. ¶ 64. But that deficiency is not fatal to their complaint. *Bausch*, 630 F.3d at 560 ("Although the complaint would be stronger [by specifying the "precise defect" alleged in a medical device], we do not believe the absence of those details . . . can support a dismissal [with prejudice] under Rule 12(b)(6)."); *Garner*, 888 F. Supp. 2d at 923–24 (plaintiff's alleged injury plus plausible allegations of product defect sufficient to withstand dismissal even in absence of allegations specifically linking alleged defects to injury suffered). "We give the plaintiff 'the benefit of imagination, so long as the hypotheses are consistent with the complaint.'" *James v. Diva Int'l, Inc.*, 803 F. Supp. 2d 945, 948 (S.D. Ind. 2011) (emphasis omitted) (quoting *Bausch*, 630 F.3d at 559). The core of the Warrens' allegations is that Jardiance carries with it a higher risk of ketoacidosis—which Tanya alleges to have experienced—as compared to other SGLT2 inhibitors or other kinds of glucose-lowering medication.

While the Manufacturers correctly point out that, under the LPLA, a trier of fact cannot "infer the existence of a defect based solely on the fact that an accident occurred[,]" *Ashley*, 666 So. 2d at 1322 (finding insufficient evidence to sustain judgment for plaintiffs after bench trial), "circumstantial evidence may be sufficient" to prove a defect under the LPLA. *Jurls v. Ford Motor Co.*, 32,125 (La. App. 2 Cir. 1/6/2000); 752 So. 2d 260, 266 (reversing directed verdict for defendants, distinguishing *Ashley*, noting LPLA imposes liability for "a characteristic" not "a 'specific' characteristic"). And the question for the Court is not whether the Warrens have alleged facts sufficient to sustain a jury verdict, but whether they have alleged facts sufficient to sustain a plausible claim to relief.

Accordingly, we hold that the Warrens' complaint plausibly states a claim for Count (I) defective design. Whether dismissal is nevertheless warranted on pre-emption grounds is considered below.

B. Count (II): Failure to Warn

The Warrens next plead that Jardiance is unreasonably dangerous in failing to provide an adequate warning. Under the LPLA,

> A product is unreasonably dangerous because an adequate warning about the product has not been provided if . . . the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users . . . of the product.

Reynolds, 172 So. 3d at 614 (quoting La. Stat. Ann. § 9:2800.57(A)).

> "Adequate warning" is defined as "a warning or instruction that would lead an ordinary reasonable user . . . of a product

> to contemplate the danger in using . . . the product and either to decline to use . . . the product or, if possible, to use . . . the product in such a manner as to avoid the damage for which the claim is made.

Id. (quoting La. Stat. Ann. § 9:2800.53(9)).

Here, as noted above, the Warrens allege that Jardiance causes damage by causing ketoacidosis. The Warrens allege further that the Manufacturers with reasonable care should have known and warned of such danger. Specifically, the Warrens allege that proper analysis demonstrated or would have demonstrated that Jardiance causes increased ketones in animals, Pls.' Am. Compl. ¶ 35(b), and in humans, *id.* at (f), and that drugs like Jardiance with selectivity for the SGLT1 receptor may cause ketoacidosis. *Id.* at (a), (c). The Warrens allege the Manufacturers nevertheless failed to warn users of Jardiance and their doctors of the risks of ketoacidosis even when requested by the FDA to do so. *Id.* at ¶¶ 39–41, 131(a), (b). Moreover, the Warrens allege that, if Tanya and her endocrinologist had known of Jardiance's risks, Tanya "would not have been prescribed Jardiance, and . . . would not have taken Jardiance, or [Tanya] would have been adequately monitored for its side effects . . . ." *Id.* at ¶ 52.

The Warrens' complaint thus plausibly states a claim for Count (II) failure to warn. The Manufacturers' motion is therefore DENIED as to that claim. Again, whether dismissal as to Lilly is nevertheless warranted on pre-emption grounds is considered below.

C. Count (VI): Breach of Express Warranty

The Warrens plead finally that Jardiance is unreasonably dangerous in failing to conform to an express warranty of the manufacturer. Under the LPLA,

> A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the [plaintiff] or another person . . . to use the product and the [plaintiff's] damage was proximately caused because the express warranty was untrue.

Reynolds, 172 So. 3d at 615 (quoting La. Stat. Ann. § 9:2800.58). The plaintiff therefore must allege and ultimately prove: "(1) a specific express warranty that induced [her] to use [the product], (2) . . . that the warranty was untrue, and (3) . . . that the failure to conform to that express warranty caused [her] injuries." *Id.*

"The LPLA makes it very clear that in order for the manufacturer to be liable, there must be a specified stated warranty, i.e., *express*." *Id.* (original emphasis) (distinguishing express warranty from "general[] . . . expectation" that car's air bags would mitigate injury).

> [T]he LPLA defines "express warranty" as . . . a representation, statement of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship possesses specified characteristics or qualities or will meet a specified level of performance. "Express warranty" does not mean a general opinion about or general praise of a product. A sample or model of a product is an express warranty.

Sudderth v. Mariner Elec. Co., Inc., 16-5 (La. App. 5 Cir. 5/26/16); 193 So. 3d 552, 561 (quoting La. Stat. Ann. § 9:2800.53(6)). "An express warranty is a guarantee which the manufacturer . . . of a good voluntarily undertakes and extends to its customer. It is not a

warning[.]" *Hopkins v. Am. Cyanamid Co.*, 95-1088 (La. 1/16/96); 666 So. 2d 615, 623; *see also Hopkins v. Am. Cyanamid Co.*, 26,721 (La. App. 2 Cir. 4/8/96); 674 So. 2d 1042, 1044 (distinguishing express warranty from failure to warn); *Florence v. Clinique Labs., Inc.*, 347 So. 2d 1232, 1236 (La. Ct. App. 1977) (distinguishing express warranty from statements "in the nature of a sales pitch arising in the ordinary course of merchandising").

The Warrens have not pleaded the existence of an express warranty. The Warrens instead refer generally to the Manufacturers' "package inserts, marketing, and other written materials intended for physicians and the public . . . ," Pls.' Am. Compl. ¶ 119, as the source of the alleged warranty, but allege only that those materials either represented that Jardiance is "safe, effective, fit and proper for its intended use," *id.*, or omitted "language that would suggest Jardiance has been associated with diabetic ketoacidosis . . . ." *Id.* at ¶ 121. Even if the Manufacturers' materials—which the Warrens have not attached to their complaint or directly quoted—expressly state that Jardiance was "safe" and the like, that does not rise from a "general opinion" to a "representation, statement of alleged fact or promise" about Jardiance. La. Stat. Ann. § 9:2800.53(6); *see Florence*, 347 So. 2d at 1236 (cosmetics purporting to be "just the products for you" do not state actionable warranty). And any claim predicated on the Manufacturers' omitting to communicate the risks of ketoacidosis states a failure-to-warn claim, not a breach-of-warranty claim.

We conclude that the Warrens' complaint does not plausibly state a claim for Count (VI) breach of express warranty. The Manufacturers' motion is therefore GRANTED as to that claim and it is DISMISSED WITHOUT PREJUDICE.

III. Pre-Emption

The Manufacturers' motion seeks to dismiss Count (I), the defective-design claim, as pre-empted by the Federal Food, Drug, and Cosmetic Act (FDCA) and FDA regulations. Lilly moves to dismiss both Counts (I) defective design and (II) failure to warn as pre-empted by the same law but for a different reason. To avoid "unnecessary constitutional adjudication," federal courts "are supposed to explore all nonconstitutional grounds of decision first[.]" *Ameritech Corp. v. McCann*, 403 F.3d 908, 911 (7th Cir. 2005). Having determined that Count (I) defective design satisfies Rule 8 as pleaded, we shall next address the Manufacturers' motion, and because Count (I) and Count (II) failure to warn satisfy Rule 8 as pleaded, we shall then address Lilly's motion.

Pre-emption is an affirmative defense that ordinarily should be raised in a responsive pleading, not in a motion to dismiss. *Bausch*, 630 F.3d at 561. Nonetheless, we shall address this issue now because "[w]hether a particular ground for opposing a claim may be the basis for dismissal for failure to state a claim depends on whether the allegations in the complaint suffice to establish that ground, not on the nature of the ground in the abstract." *Jones v. Bock*, 549 U.S. 199, 215 (2007). The Manufacturers' and Lilly's arguments are confined to the allegations as they are set out in the Warrens' complaint, which "need not anticipate or attempt to circumvent affirmative defenses." *Bausch*, 630 F.3d at 561.

A. Background

Under the Supremacy Clause of the Constitution, U.S. Const., Art. VI, cl. 2, when state and federal law conflict, state law is pre-empted and must yield. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011). State and federal law conflict "where it is impossible for a private party to comply with both state and federal law" ("impossibility pre-emption") or where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" ("obstacle pre-emption"). *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000) (alteration and quotations omitted). The Manufacturers rely largely, and Lilly entirely, on impossibility pre-emption. The Manufacturers mention obstacle pre-emption in passing as well. Both motions invoke the Supreme Court decisions in *Wyeth v. Levine*, 555 U.S. 555 (2009), *Mensing*, and *Mutual Pharmaceutical Company, Inc. v. Bartlett*, 133 S. Ct. 2466 (2013), which considered the pre-emptive effect of the FDCA and FDA regulations on state tort law as applied to drug manufacturers, and control our decision here.

In *Levine*, plaintiffs brought a failure-to-warn claim against the manufacturer of a brand-name drug, contending that state tort law imposed a duty on the manufacturer to strengthen the drug's warning label. 555 U.S. at 560. The manufacturer responded that it was prohibited by the FDCA and FDA from using any label other than the one already approved by the FDA. *Id.* at 561. The Supreme Court found, however, that a manufacturer may strengthen its labels without prior FDA approval under the "changes being effected" ("CBE") regulation. *Id.* at 568. "[A]bsent clear evidence that the FDA

would not have approved a change to [the drug's] label" made under the CBE regulation, no impossibility finding between state and federal duties arose. *Id.* at 571.

Mensing and *Bartlett* involved suits against manufacturers of generic drugs, which are subject to a "meaningfully different" federal regulatory framework than applies to brand-name drugs, *Mensing*, 564 U.S. at 626, for failure to warn and defective design, respectively. Critically, a generic drug is required to have the identical label and design as its brand-name counterpart. *Id.* at 613 (label); *Bartlett*, 133 S. Ct. at 2475 (design). Because generic drug manufacturers cannot "independently" change the labeling or design of their drugs, *Mensing*, 564 U.S. at 620, state-law duties requiring such changes conflict with the federal "duty of sameness" and are pre-empted. *Id.* at 616. Responding to the argument that the manufacturers' compliance with both duties was possible by ceasing to sell the drug, the Supreme Court held that, under its precedents, the possibility of ceasing to act does not defeat impossibility pre-emption. *Bartlett*, 133 S. Ct. at 2477.

B. The Manufacturers' Motion

As to impossibility pre-emption, the Manufacturers' argue that any successful defective-design claim would impose on them a duty to make changes to Jardiance for which prior FDA approval would be required. The Manufacturers argue further that, because they cannot independently change the design of Jardiance, the Warrens' design-defect claim is pre-empted. We reject this argument, however, because it is contrary to *Levine* and misreads *Mensing*. Because the Manufacturers have not shown clear evidence that any changes to Jardiance requiring FDA approval would be disapproved by the FDA,

the Manufacturers are not at least at this juncture entitled to dismissal based on impossibility pre-emption, as we explain more fully below.

Regarding obstacle pre-emption, given that the Manufacturers' cursory argument was rejected by *Levine*, we reject it as well.

1. Impossibility Pre-Emption

The Manufacturer's motion references a design-defect claim against a brand-name manufacturer,[4] a configuration not confronted in *Levine-Mensing-Bartlett*. *Levine* involved a failure-to-warn claim against a brand-name manufacturer; *Mensing* involved a failure-to-warn claim, and *Bartlett*, a design-defect claim, both against generic manufacturers.

The District Court for the Eastern District of Louisiana recently ruled that pre-emption of design-defect claims against brand-name manufacturers "is a new and undecided issue" in the Fifth Circuit. *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1204 (E.D. La. 2016) (applying LPLA). So it is in the Seventh Circuit as well. Indeed, "[t]he Sixth Circuit is [still] the only appellate court that has squarely addressed the issue presented here." *Id.* Accordingly, both *Guidry* and the parties before our court rely on the Sixth Circuit's decision in *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281 (6th Cir. 2015), though they draw opposite conclusions from its holding.

[4] We have been asked to accept that Jardiance is a brand-name drug based on the briefs, as that fact does not appear on the face of the Warrens' complaint. Because claims against a generic manufacturer would be pre-empted without more, we have assumed, in the Warrens' favor, that Jardiance is a brand-name drug.

We are persuaded by the reasoning in *Yates*, consistent with the Manufacturers' arguments, that "*Levine*, *Mensing*, and *Bartlett* . . . together stat[e] the same test for impossibility pre-emption[,]" *Yates*, 808 F.3d at 296–97, and, contrary to the Warrens' argument, reject that *Bartlett* "simply does not apply to brand-name drugs . . . ." Pls.' Resp. Br., p. 11; *see Yates*, 808 F.3d at 296 (rejecting "contention that the impossibility preemption in *Mensing* and *Bartlett* is limited to generic drugs"). The unexplained assertion that the brand-name context is simply different, without accounting for why that difference should not be understood in light of the three decisions above, is not persuasive. In *Yates*, "[b]ecause the federal statutes and regulations for brand-name and generic drugs are sometimes different, . . . brand-name and generic drugs may face different impossibility preemption results . . . [,]" the court held. 808 F.3d at 297; *see Mensing*, 564 U.S. at 626 ("[D]ifferent federal statutes and regulations may . . . lead to different pre-emption results.").

Similarly, *Yates* and *Guidry* both distinguish between "pre-approval" claims, focusing on the Manufacturers' liability prior to FDA approval of Jardiance, and "post-approval" claims, focusing on their liability after FDA approval was granted. The Warrens make this distinction here as well. Pls.' Resp. Br., p. 12 ("[T]he main focus of Plaintiffs' claims is on the original design of Jardiance before FDA approval, not Defendants' failure to redesign the drug after FDA approval."). While each kind of claim may reach a different pre-emption result, both must stand or fall on the same reading of *Levine-Mensing-Bartlett*. *Compare Yates*, 808 F.3d at 297–300 (reaching same result:

both claims pre-empted), *with Guidry*, 206 F. Supp. 3d at 1206–09 (reaching different result: post-approval but not pre-approval claim pre-empted).

The Manufacturers' argument for impossibility pre-emption is attractively simple. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 564 U.S. at 620. "Plaintiffs allege [under the LPLA] that Defendants should have redesigned Jardiance[,]" but "[f]ederal law *prohibits* a drug manufacturer from changing a drug's formulation without first obtaining FDA approval . . . ." Defs.' Br. Supp., p. 19 (original emphasis). The Manufacturers conclude that the Warrens' design-defect claim is therefore pre-empted.

More specifically, the Manufacturers read *Mensing-Bartlett* to stand for two propositions: First, every successful state-law design-defect claim will impose a change on the design of drug requiring FDA approval before it is made; second, whenever the approval of a federal official can be shown to stand between a tortfeasor and the observance of a state-law tort duty, state law is pre-empted without more. The first proposition is contrary to *Bartlett*. The second proposition, its startling breadth notwithstanding, is contrary to *Levine* and incorrectly reads *Mensing*.

As to the first proposition, *Yates* rejected it as the result of "misplaced" reliance on a one-sentence dictum in *Bartlett*. 808 F.3d at 296 (citing *Bartlett*, 133 S. Ct. at 2471 ("Once a drug—whether generic or brand-name—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." (quotations and citation omitted))). *Bartlett* itself demonstrates why this reliance is misplaced.

Following *Bartlett*, a court deciding an impossibility pre-emption question "begin[s] by identifying [the defendant's] duties under state law." *Bartlett*, 133 S. Ct. at 2473. This requires asking whether state tort law imposes any duties at all, *see id.* at 2473–74 (distinguishing fault-based strict-liability and negligence regimes imposing duties from no-fault, merely cost-allocating "absolute-liability" regimes not imposing duties), and what the content is of the duties imposed. *See id.* at 2474–76 (carefully delineating duties imposed by New Hampshire tort law); *Yates*, 808 F.3d at 297–98 (carefully delineating duties imposed by New York tort law). The Manufacturers have undertaken no such case-specific analysis here, relying instead on the conclusory statement that they "should have redesigned Jardiance" under any successful design-defect claim under any state's law, or at least without specific reference to the LPLA. Defs.' Br. Supp., p. 19.[5]

Still following *Bartlett*, a court must next identify the defendant's duties under applicable federal law. *See Bartlett*, 133 S. Ct. at 2476; *Yates*, 808 F.3d at 289–99. "Before marketing a new drug, the manufacturer must submit a New Drug Application

[5] To the extent that the LPLA imposes liability only for products that are "unreasonably dangerous . . . at the time the product *left the control* of its manufacturer[,]" La. Stat. Ann. § 9:2800.54 (emphasis added), and a drug arguably leaves the control of its manufacturer for purposes of the LPLA when it is approved by the FDA, *see Guidry*, 206 F. Supp. 3d. at 1207–08, the Warrens' post-approval claim may be barred, not by pre-emption, but by the failure of a state-law duty to attach in the first place. As noted above, to avoid "unnecessary constitutional adjudication," federal courts "are supposed to explore all nonconstitutional grounds of decision first[.]" *McCann*, 403 F.3d at 911.

[(NDA)] to the FDA, which demonstrates by 'substantial evidence' that the medication is efficacious. 21 U.S.C. 355(d)(5)." *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 391 (7th Cir. 2010). After the NDA has been approved, "the applicant must notify" the FDA of any change to the terms of the NDA "beyond the variations already provided for in the NDA." 21 C.F.R. § 314.70(a)(1)(i).

Federal regulation defines three classes of changes: "major changes," "moderate changes," and "minor changes." *Id.* at (b), (c), (d). Only major changes require "approval prior to distribution" of the altered drug. *Id.* at (b). A major change is

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

Id. at (b)(1). Such changes "include, but are not limited to[,] . . . changes in the qualitative or quantitative formulation of the drug product[.]" *Id.* at (b)(2)(i).

A moderate change is "any change in the drug substance," etc., "that has a moderate potential to have an adverse effect on the identity," etc., "of the drug product as these factors may relate to the safety or effectiveness of the drug product." *Id.* at (c)(1). A moderate change generally requires submission to the FDA "at least 30 days prior to distribution . . . [,]" *id.* at (c), and if the FDA disapproves the change after distribution has started, the FDA "may order the manufacturer to cease distribution of the drug product(s) made with the manufacturing change." *Id.* at (c)(7). The procedure for moderate changes is the "CBE regulation" discussed in *Levine*. 555 U.S. at 568 (quoting 21 C.F.R. §

314.70(c)(6)(iii)(A), (C)); 21 C.F.R. § 314.70(c)(3) (application for change must be labeled "Supplement—Changes Being Effected").

On the basis of what a major change "include[s], but [is] not limited to[,]" 21 C.F.R. § 314.70(b)(2)(i), but without any consideration of the provision that a major change must have "substantial potential to have an *adverse* effect . . . relat[ing] to the safety or effectiveness of the drug product[,]" *id.* at (b)(1) (emphasis added), *Yates* concluded that "reduc[ing] the amount of estrogen [in a birth-control patch] from 0.75 mg/patch to 0.6 mg/patch" would be a major change under the "plain meaning of the regulation[.]" 808 F.3d at 298. Here again, the Manufacturers have undertaken no such case-specific analysis. Indeed, because it is not clear precisely what changes the LPLA would impose on the Manufacturers simply from the face of the Warrens' complaint, such analysis may not yet be possible. *See Bausch*, 630 F.3d at 561 (complaint need not anticipate affirmative defenses).

In short, "[i]mpossibility pre-emption is a *demanding* defense." *Levine*, 555 U.S. at 573 (emphasis added). Under the analysis set out in *Bartlett*, and as applied by *Yates*, the Manufacturers must specifically identify which state and federal duties allegedly conflict. *Bartlett* did not reach, and the Manufacturers are not entitled to rely on, the "sweeping conclusion" that every successful state-law design-defect claim will impose a change on the design of drug requiring FDA approval before it is made. *Yates*, 808 F.3d at 296.

But even assuming the Manufacturers have correctly stated the applicable state and federal duties, that is, assuming that the Warrens' successful design-defect claim

under the LPLA would require a major change to Jardiance as defined by federal regulation, the Manufacturers still must establish the second proposition arising from *Mensing*: whenever acts required for observance of a state-law duty require the approval of a federal official, state law is pre-empted without more.[6] There are statements in *Mensing* which, taken in isolation, lend support to this general proposition. 564 U.S. at 620 ("The question for 'impossibility' is whether the private party could *independently* do under federal law what state law requires of it." (emphasis added)), 623–24 ("[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." (emphasis added)).

[6] Contrary to the position taken by the Warrens and the *Guidry* court, we find no meaningful distinction between pre-approval claims and post-approval claims in this respect. Pls.' Resp. Br., p. 11–13; *Guidry*, 206 F. Supp. 3d at 1209. The Warrens correctly point out that there is of course no federal duty to market unreasonably dangerous drugs. Pls.' Resp. Br., p. 12. But they omit the clear federal duty not to market *any* drug without FDA approval. 21 U.S.C. § 355(a) ("No person shall introduce . . . into interstate commerce any new drug, unless an approval of an [NDA] . . . is effective with respect to such drug."). Thus, if post-approval claims are pre-empted without more because observance of state law at some stage requires federal approval, so too must pre-approval claims be.

The Manufacturers could have chosen never to market Jardiance in the first place, but we agree with the *Yates* court that this "never start selling" argument is indistinguishable from the "stop selling" argument squarely rejected in *Mensing* and again in *Bartlett*. *Yates*, 808 F.3d at 300. If "the mere fact that a manufacturer may avoid liability by leaving the market does not defeat a claim of impossibility[,]" *Bartlett*, 133 S. Ct. at 2478 n.5, the Court cannot perceive, nor have the Warrens shown, why the mere fact that a manufacturer may avoid liability by never entering the market should lead to a different result. Accepting either proposition would "render impossibility pre-emption 'all but meaningless'" on the same terms. *Id.* at 2477 n.3 (quoting *Mensing*, 564 U.S. at 621).

The problem with accepting this general proposition as controlling is that it is directly contrary to the plain holding of *Levine*. There, as acknowledged in *Mensing*, 564 U.S. at 624 n.8, the CBE regulation interposed federal approval between the manufacturer and the observance of its state-law duty to moderately change its drug by strengthening its label. Though the CBE regulation permitted the manufacturer to act first, subject to the FDA's later approval, it is clear that the mere act of distributing a moderately changed product subject to later approval, or of making a moderate change that is later disapproved, would not in itself satisfy a manufacturer's state-law duty. Precisely for this reason, *Levine* permitted the manufacturer to show "clear evidence" that the FDA would later disapprove the change, only then establishing the impossibility of dual compliance and the manufacturer's entitlement to pre-emption. *Levine*, 555 U.S. at 571. In short, the manufacturer in *Levine* could not observe its state-law duty *without federal approval*.

Mensing could simply have overruled *Levine* on this point. But *Mensing* expressly did not overrule *Levine*. *Mensing*, 564 U.S. at 624 (*Levine* is "not to the contrary."), *id.* at n.8 (*Levine*'s "analysis is consistent with our holding today."). *Mensing* may instead have limited *Levine* to the arbitrarily defined subset of pre-emption cases in which federal law interposes federal approval of an action after the action is taken rather than before. But the Supreme Court "does not normally . . . so dramatically limit[] earlier authority *sub silentio*." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 18 (2000). The apparent conflict between *Levine* and *Mensing* disappears, however, if the "general expressions" in *Mensing* on which the Manufacturers rely are "taken in connection with

the case in which those expressions are used." *Lilly Indus., Inc. v. Health-Chem Corp.*, 974 F. Supp. 702, 706 (S.D. Ind. 1997) (Hamilton, J.) (quoting *Cohens v. Virginia*, 19 U.S. (6 Wheat.) 264, 399 (1821) (Marshall, J.)).

Mensing first determined that the defendant generic manufacturer could satisfy its state-law duty to provide a stronger warning neither by making a labeling change under the CBE procedure nor by direct warnings to physicians via "Dear Doctor" letters because federal law did not permit a generic manufacturer to do either. 564 U.S. at 616. The FDA, as amicus for the plaintiffs, argued that the misbranding provision of the FDCA, 21 U.S.C. § 352(f)(2), required "[g]eneric manufacturers that become aware of safety problems [to] ask the [FDA] to work toward strengthening the label" in concert with the brand-name manufacturer, to whose label the generic label is yoked by the federal "duty of sameness . . . ." *Mensing*, 564 U.S. at 616. The FDA could then have "worked with" the brand-name manufacturer to craft a new, adequate label. *Id.* The Court assumed without deciding that such a duty to "ask the [FDA] to work toward" existed. *Id.* at 617.

The Court nevertheless rejected the FDA's and the plaintiffs' argument that the possibility of "ask[ing] the FDA for help" defeated pre-emption:

> The Manufacturers "freely concede" that they could have asked the FDA for help. If they had done so, and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to [compliance with state law]. . . .

> Accepting [the FDA's and the plaintiffs' argument] would render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory. We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. . . . [I]t is certainly possible that, had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label. Of course, it is also *possible* that the Manufacturers could have convinced the FDA to reinterpret its regulations in a manner that would have opened the CBE process to them. . . . [I]t is also *possible* that, by asking, the Manufacturers could have persuaded to rewrite its generic drug regulations entirely or talked Congress into amending the [FDCA]. If these conjectures suffice to [defeat pre-emption] . . . , it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. . . .
>
> To be sure, whether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine. But this is not such a case. Before the Manufacturers could satisfy state law, the FDA . . . had to undertake a special effort permitting them to do so. To decide these cases, it is enough to hold that when 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.

Id. at 619–21, 623–24 (original emphasis, citations omitted).

Two conclusions flow from the above-quoted passages: First, "independence" for pre-emption purposes is not a binary switch. The question for pre-emption is whether a private party can act "sufficiently" independently under federal law to comply with state law. *Id.* at 623. Second, *Mensing* carefully avoided the holding that the Manufacturers advance here; in fact, that question was simply not before the Court at the time. *Mensing*

rejected the need for extraordinary or special pleading with a federal agency, private third parties, and Congress for their co-operation in changing or working around federal law. *See id.* at 623 ("special effort"), 623–24 ("special permission and assistance"). *Mensing* did not reject, and, it seems to us, carefully avoided rejecting, the need for submitting a change for the FDA's approval according to the terms of federal law. In other words, *Mensing* rejected as defeating pre-emption, not the possibility of dual compliance *within* the terms of federal law, but the possibility of dual compliance *outside* them.

In this light, the restated question for decision here is whether a major change to a brand-name drug should be treated under the applicable legal principles like a moderate change to a brand-name drug or like any change to a generic drug. We favor the former, for three reasons.

First, the only distinction between the approval of moderate and major changes is the difference in timing. Major changes require FDA approval before distributing the changed drug, 21 C.F.R. § 314.70(b), while moderate changes may be distributed first subject to later approval. *Id.* at (c). But this difference in itself is simply not relevant to any pre-emption consideration. As noted above, *Levine*'s clear-evidence requirement turns on the assumption that a moderate change later rejected would not satisfy the manufacturer's state-law duty. And there is nothing in *Levine*, *Mensing*, or *Bartlett*, nor in the FDCA or federal regulation, to suggest that moderate changes are presumptively, rebuttably, or revocably approved, such that moderate change-making is qualitatively more independent, or less dependent on the FDA, in a legal sense than is major change-making. The timing difference is *only* a timing difference.

Second, *Levine* suggests that clear evidence of FDA rejection was required in part because the manufacturer was not entitled to rely on the assumption that the FDA would reject a change that by hypothesis makes the manufacturer's drug safer. *See* 555 U.S. at 570 ("[T]he very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept—neither [the manufacturer] nor the United States [as amicus for the manufacturer] has identified a case in which the FDA has done so."). That is only a hypothesis: the FDA may balance the risk and utility of a proposed change differently than did a state tort jury. But a manufacturer should be required to show this to be so.

Third, any pre-emption analysis "must be guided by two cornerstones of . . . pre-emption jurisprudence": "the purpose of Congress" read against the "assumption" that, "in a field which the States have traditionally occupied, . . . the historic police powers of the States were not be superseded by the Federal Act . . . ." *Levine*, 555 U.S. at 565 (quotations omitted).[7] *Levine* found, and neither *Mensing* nor *Bartlett* questioned, that, in crafting the FDCA, "Congress took care to preserve state law" as to suits over drugs by its inclusion of a savings clause and its failure expressly to pre-empt suits over drugs while expressly pre-empting suits over medical devices. *Id.* at 567. Congress's "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is

[7] It is true that pre-emption "is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce[.]" *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963). But these cases have moved far beyond the "physical impossibility" standard of *Florida Lime*, and the Manufacturers have not argued, nor could they, that dual compliance is "physical[ly] impossib[le]." *Id.*

powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. Our conclusion here is entirely consistent with this congressional purpose; the Manufacturers' position is not. *See Guidry*, 206 F. Supp. 3d at 1207 (answering in the negative, "[D]id Congress intend the FDA to be judge and jury in deciding whether a brand name drug is safe and effective? . . . Are drug manufacturers shielded from liability if their drug causes harm due to a defect in design simply because the FDA said the drug was safe?").

In sum, because the Manufacturers have neither identified the specific state and federal duties at stake in this case, nor shown clear evidence that, if FDA approval of the state-mandated change is required, such approval would be withheld, the Manufacturers are not now entitled to dismissal based on impossibility pre-emption.

2. Obstacle Pre-Emption

The Manufacturers in one terse paragraph have also raised an obstacle pre-emption defense to any pre-approval claim. Defs.' Br. Supp., pp. 21–22. We reject this defense for the same reasons relied upon in *Levine* as to FDA-approved labels: that, in general, state tort suits complement, rather than frustrate, the accomplishment of the FDA's regulatory goals. *See Levine*, 555 U.S. at 573 (rejecting manufacturer's argument that FDA approval is "both a floor and a ceiling for drug regulation"), 574 (noting Congress's refusal to enact express pre-emption provision in FDCA's 70-year history), 579 ("[T]he FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation."). Though "some state-law

claims might well frustrate the achievement of congressional objectives," *id.* at 581, the Manufacturers have not shown in any persuasive fashion that this is one of them. *See id*.

The Manufacturers' motion to dismiss is therefore DENIED as to Count (I) defective design.

C. Lilly's Motion

The pre-emption defense raised in Lilly's motion presents a far easier question. Lilly argues that, because it does not and has never held the NDA for Jardiance, it is in the same position as a generic manufacturer. Federal law prohibits any person but the NDA holder from making changes to a drug; Lilly is not the NDA holder; therefore, like a generic manufacturer, no matter what specific duties the LPLA might impose on it as to the design and labeling of Jardiance, Lilly is prohibited by federal law from observing them and the Warrens' claims thus are pre-empted. Lilly's Br. Supp., pp. 9–11. Regarding the Warrens' claims for Counts (I) defective design and (II) failure to warn, we agree with Lilly.

The Warrens' complaint contains no allegations as to who holds the Jardiance NDA. On a motion to dismiss, a court ordinarily may not consider matters outside the pleadings without converting the motion into one for summary judgment with notice to the litigants and an opportunity to respond. *Travel All Over the World, Inc. v. Kingdom of Saudi Arabia*, 73 F.3d 1423, 1430 (7th Cir. 1996). But "[a] court may consider judicially noticed documents without converting" the motion to dismiss. *Menominee Indian Tribe of Wisconsin v. Thompson*, 161 F.3d 449, 456 (7th Cir. 1998). "Judicial notice of . . .

documents contained in the public record[] and reports of administrative bodies is proper." *Id.*

As urged by Lilly, we judicially notice the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, or the "Orange Book." The Orange Book is a "publically available list of drugs which have been approved [by the FDA] for safety and effectiveness." *Abbot Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 927 (N.D. Ill. 1995); *see, e.g.*, *Morris v. Wyeth, Inc.*, No. 9-854, 2012 WL 601455 (W.D. La. Feb. 23, 2012) (noticing Orange Book entry identifying defendant as "one of the reference listed drug . . . holders" for certain drug (alterations omitted)). As the "applicant holder" (that is, the NDA holder) for Jardiance, the Orange Book lists "Boehringer Ingelheim Pharmaceuticals Inc." FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations*, https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm (search by "Proprietary Name, Active Ingredient or Application Number," search "Jardiance") (last visited Aug. 24, 2017).

As noted above, "[b]efore marketing a new drug, the manufacturer must submit a[n] [NDA] to the FDA, which demonstrates by 'substantial evidence' that the medication is efficacious. 21 U.S.C. 355(d)(5)." *Mason*, 596 F.3d at 391. After the NDA has been approved, "the applicant must notify" the FDA of any change to the terms of the NDA "beyond the variations already provided for in the NDA." 21 C.F.R. § 314.70(a)(1)(i). An "applicant" is "any person who submits an NDA . . . or supplement to an NDA . . . to obtain FDA approval of a new drug and any person who owns an

approved NDA . . . .” *Id.* at § 314.3. There is no provision under which a nonapplicant may submit a change to an approved NDA.

The Sixth Circuit has held that, without an NDA, a manufacturer has “no more power to change the label” or, by extension, the design of a drug than does a generic manufacturer. *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 940 (6th Cir. 2014). That jibes with our view. Without such power, Lilly cannot independently comply with any duty under the LPLA to change the design or labeling of Jardiance. The LPLA is therefore pre-empted with regard to these claims against Lilly. *See id.*

Accordingly, Lilly’s motion is GRANTED. Because amendment would be futile, Counts (I) defective design and (II) failure to warn are DISMISSED WITH PREJUDICE as to Lilly. They survive only against Boehringer.

Conclusion

For the above reasons, the Manufacturers’ motion is GRANTED as to Counts (III) negligence, (IV) negligent misrepresentation, (V) breach of implied warranty of merchantability, (VII) fraudulent misrepresentation, (VIII) fraudulent concealment, (IX) deceptive acts under Indiana’s Deceptive Consumer Sales Act, and (XI) punitive damages. Those claims are DISMISSED WITH PREJUDICE.

The Manufacturers’ motion is GRANTED as to Count (VI) breach of express warranty. That claim is DISMISSED WITHOUT PREJUDICE. The Warrens may seek leave to replead the claim within fourteen days from the date of this Order.

The Manufacturers' motion is DENIED as to Counts (I) defective design and (II) failure to warn, and derivatively as to Count (X) loss of consortium.

Lilly's motion is GRANTED as to Counts (I) defective design and (II) failure to warn. Those claims as to Lilly are DISMISSED WITH PREJUDICE.

Date: 9/8/2017

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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