UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JONATHAN RASKAS, personally and as administrator of the ESTATE OF RALPH RASKAS, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC.; ACTAVIS ELIZABETH, LLC; and JOHN DOE DEFENDANTS, Defendants.	)	Case No. 4:17-CV-2261 RLW

MEMORANDUM AND ORDER

Teva Pharmaceuticals, USA, Inc. (Teva) and Actavis Elizabeth, LLC (Actavis) move this Court to dismiss the claims against them pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. [ECF Nos. 8, 13]

Background

Accepting as true the allegations in the complaint, *see Tension Envelope Corp. v JBM Envelope Corp.*, 876 F.3d 1112, 1116 (8th Cir. 2017), the following led to the untimely death of Ralph Raskas (Raskas).

When 19 years of age, Raskas sought emergency room treatment in a Missouri hospital for nausea and vomiting. (Compl. ¶12, ECF No. 5.) He was treated with an intravenous injection of metoclopramide. (*Id.* ¶13.) This metoclopramide was manufactured by Teva. (*Id.*) On discharge, he was prescribed ten milligram dosages of metoclopramide to be taken four times a day. (*Id.* ¶14.) A five-day supply of the prescription was dispensed by a pharmacy the same day. (*Id.*) This metoclopramide was manufactured by Actavis. (*Id.* ¶15.) Raskas took the

metoclopramide and subsequently developed a movement disorder. (*Id.* ¶¶15-17, 19.) The disorder caused Raskas pain and restlessness in his legs and led to him having to take a medical leave from a six-year medical school program. (*Id.* ¶¶11, 18.)

Raskas pursued treatment at a Movement Disorders Center and with a neuropsychiatrist specializing in movement disorders. (*Id.* ¶20-21.) The specialist diagnosed him as having "'drug-induced acute akathisia." (*Id.* ¶21.) Because of the pain and akathisia, Raskas attempted suicide three times; tragically, he succeeded on the third attempt. (*Id.* ¶23-25.)

Jonathan Raskas (Plaintiff), his father and the administrator of his estate, alleges that metoclopramide caused Raskas' neurological injuries and suicide. (*Id.* ¶¶ 25-38, 50.)

Plaintiff further alleges that Teva and Actavis, as manufacturers of the generic form of metoclopramide, breached their duty to report any adverse effects of the drug to the Food and Drug Administration (FDA) and to propose to the FDA a stronger warning label. (*Id.* ¶53-54.)

Plaintiff seeks relief from Teva and Actavis for the death of Raskas under claims of strict liability for the defective design of metoclopramide (Count I); strict liability for the failure to warn of the serious health risks resulting from taking metoclopramide (Count II); negligent design of metoclopramide (Count III); negligent failure to warn of the serious health risks (Count IV); a negligent quality system that did not identify the serious health risks (Count V); a negligent failure to modify the warning labels for metoclopramide, including to incorporate in those labels the adverse findings of the European Union (Count VI[1]); and, pursuant to

[1]Plaintiff mistakenly labels this count as "Count VII."

Mo.Rev.Stat. §§ 537.080, 537.090, the wrongful death of Raskas (Count VII[2]). Plaintiff also brings a claim for loss of consortium (Count VII).

Citing *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466 (2013), Teva and Actavis seek the dismissal of all claims against them as being preempted by federal law. Plaintiff argues preemption does not apply.

Discussion

Rule 12(b)(6) Standard. "To survive a 12(b)(6) motion to dismiss, 'a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *McShane Constr. Co. v. Gotham Ins. Co.*, 867 F.3d 923, 927 (8th Cir. 2017) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id.* (quoting *Iqbal*, 556 U.S. at 678). "'[D]etermining whether a complaint states a plausible claim for relief … [is] a context-specific task that requires [this] [C]ourt to draw on its judicial experience and common sense.'" *Id.* (quoting *Iqbal*, 556 U.S. at 678-79) (second and third alterations in original).

Counts I and III: Design. In Count I, Plaintiff alleges Teva and Actavis are strictly liable for defects in the design of metoclopramide; in Count III, he alleges they were negligent in designing the drug.

The metoclopramide taken by Raskas was manufactured by Teva or Actavis.[3] Metoclopramide is a generic form of Reglan. *PLIVA,* 564 U.S. at 609. Plaintiff alleges the

[2]This count follows Count VI, but is labeled "Count VI." For ease of reference, the Court will refer to the mislabeled counts by the order in which they appear in the Complaint, e.g., "Count VII" will be referred to as Count VI and "Count VI" will be referred to as Count VII.

[3]Plaintiff often refers to "Reglan/metoclopramide" in his complaint; however, he specifically identifies Teva and Actavis as manufacturers of the metoclopramide he was given in May 2015.

metoclopramide "was defective in design and/or formulation." (Compl. ¶64.) "Missouri … imposes design defect liability if the plaintiff establishes 'the product, as designed, is unreasonably dangerous and therefore "defective," and that the demonstrated defect caused [the plaintiff's] injuries.'" *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1140 (8th Cir. 2014) (quoting *Nesselrode v. Exec. Beechcraft, Inc.*, 707 S.W.2d 371, 375-76 (Mo. 1986) (en banc)). Teva and Actavis argue that Plaintiff's design defect claims are preempted by federal law.

"Where state and federal law directly conflict, state law must give way." *Mensing*, 564 U.S. at 617. "[S]tate and federal law conflict where it is impossible for a private party to comply with both state and federal requirements." *Id.* at 618. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620.

The difference in the procedures of the Food and Drug Administration (FDA) for approving brand-name drugs and generic drugs informs the Court's consideration of the preemption question. A brand-name drug is approved only after a new-drug application is submitted. *Bartlett*, 133 S.Ct. at 2470. This application "is a compilation of materials that must include 'full reports of [all clinical] investigations,' [21 U.S.C.] § 355(b)(1)(A), relevant nonclinical studies, and 'any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source.'" *Id.* at 2470-71 (quoting 21 C.F.R. §§ 314.50(d)(2) and (5)(iv)(2012)). The application "must also include 'the labeling proposed to be used for such drug.'" *Id.* at 2471 (quoting 21 U.S.C. § 355(b)(1)(F) and 21 C.F.R. § 314.50(c)(2)(i)). "The FDA may approve [a new-drug application] only if it determines that the drug in question is 'safe for use' under 'the conditions

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For purposes of the instant motion, therefore, the Court addresses only the issue of metoclopramide and not the brand-name form, Reglan.

of use prescribed, recommended, or suggested in the proposed labeling thereof.'" *Id.* (quoting 21 U.S.C. § 355(d)).

On the other hand, "a generic drug may be approved with the same level of clinical testing required for approval of a new brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key respects." *Id.* "First, the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same 'active ingredient' or 'active ingredients,' 'route of administration,' 'dosage form,' and 'strength' as its brand-name counterpart." *Id.* (quoting 21 U.S.C. §§ 355(j)(2)(A)(iv)). "Second, a proposed generic must be 'bioequivalent' to an approved brand-name drug." *Id.* (quoting 21 U.S.C. § 355(j)(2)(A)(iv)). Third, the labeling proposed for the generic drug must be "the *same* as the labeling approved for the [approved brand-name] drug.'" *Id.* (quoting 21 U.S.C. § 355(J)(2)(A)(v)) (alteration in original). "Generic manufacturers are … prohibited from making any unilateral changes to a drug's label." *Id.* (citing 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10)).

And, "[o]nce 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.'" *Id.* (quoting 21 C.F.R. § 314.70(b)(2)(i)).

In *Fullington v. Pfizer, Inc.*, 720 F.3d 739 (8th Cir. 2013), the court held that a "logical corollary" of the preemption by federal regulations of suits seeking to impose tort liability on a generic manufacturer's labeling decisions was "that certain design defect claims are preempted as well." *Id.* at 742. This is so because a generic drug manufacturer is prohibited from unilaterally redesigning the drug. *Id.* (citing *Bartlett*, 133 S.Ct. at 2474-76). In *Brinkley*, 772

F.3d at 1140-41, the court held that a plaintiff's claims of design defect of metoclopramide were preempted when the only way the manufacturer could "avoid liability under Missouri law" was by redesigning the product. In so holding, the court specifically rejected an argument similar to that of Plaintiff's: that there is no preemption because the imposition of design defect liability in Missouri is based on "'the concept of unreasonable danger'" and is an ultimate issue to be decided by the jury. *Id.* (quoting *Nesselrode*, 707 S.W.2d at 375-76. "[Plaintiff] places too much weight on Missouri's approach to determining unreasonable danger." *Id.* at 1140. Moreover, the Court notes that the claim of a defectively-designed generic drug found by the Supreme Court in *Bartlett*, 133 S.Ct. at 2473, to be preempted was based on a state's adoption of Section 402A of the Restatement (Second) of Torts. Plaintiff bases his claim on Missouri's adoption of Section 402A.

Plaintiff seeks to distinguish his design defect claims from those presented in *Bartlett* and *Brinkley* by arguing that Teva and Actavis are liable for their design defect and negligent design because they could have "stopped selling metoclopramide to otherwise healthy young people[4] suffering from nausea and vomiting." (Pl.'s Resp. at 17, ECF No. 20 (footnote added)). This effort is unavailing. Neither Teva nor Actavis is required to stop selling metoclopramide in order to avoid liability under Missouri law for design defect. *See Brinkley,* 772 F.3d at 1141 (holding that, under the impossibility preemption doctrine, a manufacturer of a generic drug was not obligated to leave the market to avoid liability under Missouri law for an alleged design defect); *Bartlett*, 133 S.Ct. at 2477 (rejecting "'stop-selling' rationale as incompatible with [the Supreme

[4]Raskas was not within the pediatric age group when taking metoclopramide. *See* 21 C.F.R. § 201.57(c)(9)(iv)(A) (defining, for purposes of prescription drug labels, the pediatric age group as being from birth to sixteen (16) years).

Court's] pre-emption jurisprudence"). Insofar as Plaintiff's argument is that the warnings for metoclopramide should include an-age related caution, his position is addressed below.

Citing *Strickland v. Taco Bell Corp.*, 849 S.W.2d 127 (Mo.Ct.App. 1993), Plaintiff further argues that Teva may be held liable for a negligent design because it made promises on its website to exceed regulatory requirements for pharmaceutical drugs. The question in *Strickland* was whether a manager of defendant was entitled to summary judgment on claims he negligently rendered services to the plaintiffs' semi-conscious father by moving him to a bench, slumping him over a table, and leaving him there. *Id.* at 133. The father fell and later died from his resulting injuries. *Id.* The court held that the plaintiffs had stated a claim against the manager for negligently performing a duty he had gratuitously undertook toward the father. *Id.* Assuming, without deciding, that Teva made such promises, its undertaking does not affect the pre-emption analysis because the only actions he could take to avoid liability under Plaintiff's theory of a negligent-undertaking-of-an-act are those preempted by impossibility, *I.e.*,, "changing its product, changing its labeling, or leaving the market." *Brinkley*, 772 F.3d at 1141.

Counts II and IV: Warnings. In these two counts, Plaintiff alleges that Teva and Actavis are liable for (a) a warning which was insufficient to alert consumers of the health risks associated with metoclopramide and (b) breaching a duty to the FDA to communicate those risks and to propose stronger warning labels.

As discussed above, the warning labels on the metoclopramide manufactured by Teva and Actavis have to be the same as the warning labels on the brand-name form, Reglan. *See Mensing*, 564 U.S. at 613. In *Mensing*, the Supreme Court "defer[red]" to the FDA's interpretation of its regulations "allow[ing] changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the

FDA's instructions."[5] *Id.* at 614. "As [*Mensing*] made clear, federal law prevents generic drug manufacturers from changing their labels." *Bartlett*, 133 S.Ct. at 2476. "When federal law forbids an action that state law requires, the state law is without effect." *Id.* at 2476-77 (internal quotations omitted). Thus, Missouri failure to warn claims based on inadequate content "are squarely preempted by federal law." *Brinkley*, 772 F.3d at 1139.

Plaintiff argues that *Mensing* does not control because it is a labeling, not warning, case. (Pl.'s Resp. at 13.) In the context of impossibility preemption, this is a distinction without a difference.

Labels of prescription drugs are to include warnings about their proper use. *See e.g.*, 21 U.S.C. § 352(f)(2)(classifying a drug as misbranded unless the label includes, inter alia, "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health . . ."); 21 C.F.R. § 201.56(e) (requiring specific information be included in prescription drug labels for older drug products,[6] including indications and usage, contraindications, warnings, adverse reactions, and dosage and administration). *See also Strayhourn v. Wyeth Pharms.*, 737 F.3d 378, 394 (6th Cir. 2013) (noting that FDA regulations consider advertising and promotional materials as labeling).

Plaintiff alleges in his complaint that because the FDA has the power under the Food and Drug Administration Amendments Act of 2007, Pub.L. No. 110-85, 121 Stat. 823 (FDAAA), to change the label of Reglan, the reference label drug (RLD) of metoclopramide, without the involvement of the drug company, Teva and Actavis had a duty – which they breached – to inform the FDA of the risks associated with metoclopramide and to propose appropriate

[5]Plaintiff's allegations in his Response of a failure to conform or failure to update are addressed below.

[6]Reglan was approved by the FDA in 1980. *Mensing*, 564 U.S. at 609.

revisions to the label. In *Mensing*, 564 U.S. at 646 n.1, the Supreme Court declined to express a view on the impact of the FDAAA on the question before it because the events at issue took place prior to 2007. An argument that the FDAAA rendered *Mensing* and *Bartlett* outdated was rejected, however, in *Wagner v. Teva Pharms. USA, Inc.*, 840 F.3d 355 (7th Cir. 2016). The court held that, although "[t]he FDAAA imposed certain obligations on generic drug manufacturers when they propose labeling changes," it "did not remove the prohibition against doing so unilaterally." *Id.* at 359. "[T]he amendments still forbid a generic-drug maker from violating the duty of sameness without FDA permission." *Id.* (internal quotations omitted). *See also Whitener v. PLIVA, Inc.*, 2011 WL 6056546, *3(E.D. La. Dec. 6, 2011) (rejecting the same argument and holding that, because the FDAAA did not change a generic drug manufacturer's ability to alter the FDA-approved brand-name label for a drug, "the *Mensing* conflict preemption analysis [did] not change because compliance with both state and federal requirements remain[ed] impossible"). This conclusion is supported by the pre-FDAAA holding in *Mensing* that preemption foreclosed the plaintiff's claims of inadequate warning even if, as the FDA argued, the generic drug manufacturer had a duty to propose stronger warning labels if the manufacturer believed such were needed. 564 U.S. at 616.

In support of his position to the contrary, Plaintiff cites *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Wyeth*, the Supreme Court rejected the drug manufacturer's argument that the plaintiff's state law claims of injuries caused by that manufacturer's failure to warn against certain types of drug administration were preempted by the impossibility doctrine. *Id.* at 568. The Court noted "an FDA regulation … permits a manufacturer to make certain changes to its label before receiving the agency's approval." *Id.* Those changes include adding or strengthening warnings or instructions about dosage and administration "to increase the safe use

of the product." *Id.* Wyeth could have unilaterally revised the label of the drug at issue and could have also discharged its state-law duty to provide a stronger warning about the risks of the type of drug administration at issue. *Id.* at 569.

Plaintiff's reliance on *Wyeth* is unavailing. As discussed above, manufacturers of generic drugs have a duty of sameness that brand-name drug manufacturers do not. *See Mensing,* 564 U.S. at 613. *See also Bartlett*, 133 S.Ct. at 2470 ("[F]ederal law prohibits generic drug manufacturers from independently changing their drugs' labels."). The Supreme Court acknowledged in *Mensing* that the distinction between generic and brand-name drugs made "little sense" to the plaintiffs who would have had recourse for their severe injuries had they taken Reglan rather than metoclopramide, but concluded that it was not its task "to decide whether the statutory scheme established by Congress is unusual or even bizarre." 564 U.S. at 625. Similarly, in *Bartlett*, 133 S.Ct. at 2480, the Court held that, although the plaintiff's tragic situation "evoke[d] deep sympathy," "a straightforward application of pre-emption law" barred her state-law tort claims against a generic drug manufacturer for the devastating, life-long injuries she suffered.[7]

Counts V and VII: Negligence and Wrongful Death. The allegations in these counts echo those of the earlier counts[8] and are similarly unavailing. *See Brinkley*, 772 F.3d at 1141 (affirming dismissal of amended complaint against generic drug manufacturer; various state-law

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[7]In his response to the motion to dismiss, Plaintiff argues that this case is also about preventing the death of another 19-year individual. (Pl.'s Resp. at 1.) In *Bartlett*, the Supreme Court held it was not free to ignore pre-emption law in the case of a woman who was severely disfigured, developed numerous physical disabilities, and became nearly blind because of the method of administration of a generic drug. Similarly, the tragic circumstances of Raskas' injuries and suicide do not excuse this Court from following Supreme Court pre-emption law.

[8]In his response to the motion to dismiss, Plaintiff states that this claim is based on his allegations of a failure to warn that metoclopramide, injected once or taken orally, could lead to serious health risks. (Resp. at 16.)

causes of action, including negligence and breach of warranties, were foreclosed by *Mensing* and *Bartlett* because only actions manufacturer could take were preempted by impossibility).

Count VI: Negligence/Violation of FDA Requirements. Plaintiff alleges in this count that Teva and Actavis failed in their duty to modify the metoclopramide labels to incorporate certain warnings. (Compl. ¶106-07.) These allegations are addressed above.

Plaintiff further alleges that Teva and Actavis had a duty to incorporate in their warnings the findings of the European Medicines Agency's Committee on Medicinal Products for Human Use. (*See* Compl. ¶ 43-49.) This argument fails for the reasons discussed above.

Plaintiff also alleges that Teva and Actavis failed to update their labels "as allowed by the FDA" and that this failure caused injury to Raskas. (Compl. ¶110.) In his response to the motion to dismiss, Plaintiff argues that Teva and Actavis failed in their duty to update their label to conform to the FDA-approved label for Reglan and that he has sufficiently alleged that Teva's and Actavis' labels were not properly updated to entitle him to discovery of the labels in effect before May 9, 2015. (*See* Resp. at 13, 14.) Teva and Actavis counter that the failure-to-update claims have not been sufficiently pled and are, regardless, futile.

"'The court should freely give leave [to amend a complaint] when justice so requires.'" *Kozlov v. Associated Wholesale Grocers, Inc.*, 818 F.3d 380, 394 (8th Cir. 2016) (quoting Fed.R.Civ.P. 15(a)) (alteration in original). "A motion to amend should be denied if the plaintiff is 'guilty of undue delay, bad faith, dilatory motive, or if permission to amend would unduly prejudice the opposing party.'" *Id.* (quoting *Williams v. Little Rock Mun. Water Works*, 21 F.3d 218, 224 (8th Cir. 1994)). This case was filed in state court in June 2017; was served in July; and was removed to this court on August 16. Six days later, Teva moved to dismiss; fourteen days

after removal, Actavis moved to dismiss. The briefing cycle on the two motions was completed on October 30. There has been no undue delay, and no showing of bad faith or a dilatory motive.

Nor do Teva and Actavis argue that they would be unduly prejudiced by leave to amend being granted Plaintiff. Rather, they argue that any amendment would be futile. "Denial of a motion for leave to amend on the basis of futility means the district court has reached the legal conclusion that the amended complaint could not withstand a motion to dismiss under Rule 12(b)(6)[.]" *Zutz v. Nelson*, 601 F.3d 842, 850 (8th Cir. 2010) (internal quotations omitted). This court has not reached that conclusion.

In *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584, 588 (6th Cir. 2013), the court held that the plaintiff's state-law claims against a manufacturer of metoclopramide were not preempted only insofar as she argued that the manufacturer's warnings did not include the language of the Reglan label in distribution at the same time and only to the extent that the failure proximately caused her injuries. The *Fulgenzi* holding was noted in *Brinkley*, as was the opposite conclusion by the Fifth Circuit in *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (per curiam). 772 F.3d at 1137. The Eighth Circuit then proceeded to address the merits of a failure-to-update claim, finding that the allegations in the complaint severed any causal relationship between her injuries and that claim. *Id.*

In the instant case, there are insufficient allegations from which to determine whether Plaintiff can establish a failure-to-update claim against Teva and Actavis. Plaintiff has asked for leave to amend his complaint. Leave shall be granted only as to his failure-to-update and failure-to-conform claims. *Cf. United States ex rel. Amrosecchia v. Paddock Labs.,LLC*, 855 F.3d 949, 956 (8th Cir. 2017) (district court did not abuse its discretion when denying plaintiff leave to file *second* amended complaint; leave was sought in a one-line request in brief opposing motion to

dismiss and did not include substance of proposed amendments). He makes reference in his concluding paragraph to being allowed to amend his claims of a negligent undertaking of an act and to adding a claim under the Missouri Merchandising Practices Act (MMPA), Mo.Rev.Stat. § 407.010 *et seq.*, based on Teva's representations on its website. Leave to amend is *not* granted as to these claims for the reasons discussed above. *Brinkley*, 772 F.3d at 1138 (affirming dismissal of MMPA claim arising from use of metoclopramide).

Conclusion

It is beyond dispute that the suffering of Ralph Raskas is tragic. The law, however, forecloses all claims in Plaintiff's complaint with the exception of those alleging a failure-to-update or a failure-to-conform the labels, including the warnings, of Teva's and Actavis' metoclopramide to match those of Reglan. Plaintiff is granted leave to amend his complaint to include only those allegations and any related loss of consortium claim. His remaining claims against Teva and Actavis are dismissed.

Accordingly, for the foregoing reasons,

IT IS HEREBY ORDERED that the motion to dismiss of Teva Pharmaceuticals USA, Inc. [ECF No. 7] and the motion to dismiss of Actavis Elizabeth LLC [ECF No. 13] are GRANTED in part and DENIED in part as set forth above.

IT IS FURTHER ORDERED that Plaintiff is GRANTED twenty days of the date of this Order in which to file a First Amended Complaint within the strictures described above.

IT IS FINALLY ORDERED that Plaintiff shall show cause within twenty days of the date of this Order why his claims against the John Doe Defendants should not be dismissed without prejudice for failure to obtain timely service. *See* Fed.R.Civ. 4(m).

Dated this 8th day of January, 2018.

Ronnie L. White

RONNIE L. WHITE
UNITED STATES DISTRICT JUDGE