IN THE CIRCUIT COURT OF THE COUNTY OF ST. LOUIS
STATE OF MISSOURI

SUSAN BERSTEIN and MARK BERNSTEIN, Parents of Decedent MICHAEL BERSTEIN	)	
Plaintiffs,	)	Cause No. 16SL-CC04344-01
vs.	)	Division 14
ACTAVIS PHARMA, INC; ZYDUS PHARMACEUTICALS (USA), INC.; KVK-TECH, INC.; MERCY CLINIC EAST COMMUNITIES; DR. DEMETRIOS V. POLITIS, D.O.; AMNEAL PHARMACEUTICALS; and MALLINCKRODT BRAND PHARMACEUTICALS, INC,	)	
Defendants.	)	

COURT ORDER and JUDGMENT

Defendants Actavis Pharma, Inc. ("Actavis"), KVK-Tech, Inc. ("KVK-Tech"), and Zydus Pharmaceuticals (USA), Inc. ("Zydus") (collectively, "Moving Drug Manufacturer Defendants") jointly move to dismiss Plaintiffs' Second Amended Petition with prejudice for failure to state a claim upon which relief can be granted pursuant to Rule 55.27(a)(6).

Plaintiffs Susan and Mark Bernstein are the parents of decedent Michael Bernstein, who is alleged to have died on May 22, 2015, in St. Louis County from prescription-opioid intoxication. Through this lawsuit, the Bernsteins seek to hold responsible Michael's medical treatment providers who are alleged to have cared for him and the manufacturers of the prescription opioids that he is alleged to have taken before he died.

Plaintiffs' Second Amended Petition ("SAP") contains twelve (12) counts. The counts under consideration by this court is this joint motion to dismiss for failure to state claims are shown in blue, below:

Count	Claim	As Against This Defendant(s)
I	Medical Malpractice-Wrongful Death	Politis, D.O.
II	Medical Malpractice	Mercy Clinic East
III	Strict Products Liability	Actavis Pharma
IV	Negligent Products Liability	Actavis Pharma
V	Strict Products Liability	KVK-Tech
VI	Negligent Products Liability	KVK-Tech
VII	Strict Products Liability	Zydus Pharma
VIII	Negligent Products Liability	Zydus Pharma
IX	Strict Products Liability	Amneal Pharma
X	Negligent Products Liability	Amneal Pharma
XI	Strict Products Liability	Mallinckrodt Brand Pharma
XII	Negligent Products Liability	Mallinckrodt Brand Pharma
XIII	MMPA Violation[1]	All drug manufacturers
XIV	Fraudulent Misrepresentation[2]	All drug manufacturers

The court takes judicial notice of its file. The court considers the pleadings, the extensive briefing, arguments of counsel and authorities cited, both in support and in opposition.

Being fully advised, the court enters its orders, below.

Federal Preemption:

First, on the question of whether plaintiffs' state law claims of strict products liability and negligent products liability alleged against the moving drug manufacturer defendants are preempted by federal law, the court finds that they are, by reason of the

[1] Although the Missouri Merchandising Practices Act ("MMPA") claims are pled against all defendant drug manufacturers, only Actavis Pharma, AVK-Tech and Zydus Pharma seek dismissal in this joint motion.
[2] The fraud claims are pled against all defendant drug manufacturers. Only Actavis Pharma, AVK-Tech and Zydus Pharma seek dismissal.

following and for the reasons stated by the drug manufacturer defendants in support of their motion.

The court considers whether plaintiffs' claims in counts III through VIII are preempted because they are premised on federal law, not based on an independent state law duty, as argued by plaintiffs. The court finds that the manufacturing drug defendants are generic manufacturers of the drugs allegedly prescribed to Michael Bernstein by his treatment providers. In their Second Amended Petition, plaintiffs' negligent and strict liability claims are based on allegations that the generic opioids were defectively designed and that the drug manufacturers failed to warn opioid users or opioid prescribers of their significant risks of addiction, overdose and death which resulted from these defective designs.

The Supremacy Clause states that federal law shall be the supreme law of the land regardless of any state laws to the contrary. U.S. Const., Art. VI, cl. 2. Thus, whenever state law conflicts with federal law, the state law must give way. *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 480 (2013). State law and federal law conflict when it is impossible for a private party to comply with both state and federal requirements. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); *Bartlett*, 570 U.S. at 480; *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

Federal law requires different duties of brand-name manufacturers as compared to generic drug manufacturers. 21 U.S.C. § 355(j)(2)(A); *Mensing*, 564 U.S. at 612-3. While brand name manufacturers must prove that their drugs are safe and effective and that the proposed label is accurate and adequate through clinical testing, generic drug manufacturers must only show that its warning label is the same as the brand name's label. 21 U.S.C. §§ 355(b)(1), 355(j)(2)(A)(v). Generic drug manufacturers have a federal duty

of "sameness;" they are not permitted to unilaterally change a generic drug's label, not even to strengthen a warning, (21 U.S.C. § 355(j)(4)(G); *Mensing*, 564 U.S. at 614) or to change a drug's design (*Bartlett*, 570 U.S. at 483-84.).

The rule of sameness applies to claims that a drug has been misbranded as well. Misbranded drugs are those whose labels do not bear adequate warnings against unsafe dosage, methods, or duration of administration as are necessary to protect users. *Mensing* at 616. While courts and the FDA have acknowledged that generic drug manufacturers who become aware of safety problems must ask the FDA to work toward strengthening the label warning,[3] generic manufacturers still may not change a label unilaterally. *Id.* Additionally, generic manufacturers are not required to stop selling an allegedly misbranded or unsafe drug in order to comply with both state and federal law nor to avoid liability. *Id*.; *Bartlett*, at 483-84.

In Missouri, a products liability claim arises when (1) a defendant transferred a product in the course of his business, (2) the product was used in a reasonably anticipated manner, (3) that product was then in a defective condition such that it was unreasonably dangerous when put to its anticipated use or the product was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, and (4) the plaintiff was damaged as a direct result of the product's defective condition or due to the product being sold without adequate warning. § 537.760 R.S.Mo. Strict liability will be imposed on drug manufacturers for defects in unavoidably unsafe products only if the

[3] In *Mensing*, the court noted that the FDA traces this duty to 21 U.S.C. §352(f)(2), which provides that a drug is "misbranded … [u]nless its labeling bears … adequate warnings against … unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." (quoting U.S. Brief 12) *Id.* However, the court held that, even assuming such federal duty exists to seek FDA assistance to strengthen the corresponding brand-name label, this still would not have satisfied their state tort-law duty to provide adequate labeling. "State law demanded a safer label; it did not instruct manufacturers to communicate with the FDA about the possibility of a safer label." *Id*. at 619.

manufacturer failed to warn of the drug's dangerous propensities of which it either knew or should have known. *Pollard v. Ashby*, 793 S.W.2d 394, 398 (Mo. App. E.D. 1990); *Racer v. Utterman*, 629 S.W.2d 387, 393 (Mo. App. 1981).

Here, plaintiffs have brought claims of strict products liability and negligent products liability against the defendant drug manufacturers. These counts are based on the premise that the generic drugs produced by defendants were misbranded, were defective in design, and were unreasonably dangerous to users when put to a reasonably anticipated use. The Supreme Court has been clear that generic drug manufacturers only have a duty to ensure their labels are the same as brand-name manufacturers. *Mensing* at 612-3. The brand-name manufacturers bear the burden to ensure the accuracy and adequacy of a drug's label, not the generic drug manufacturers. *Id.* To permit plaintiffs' products liability claims to proceed under Missouri law, based on failure to warn or defective design, would require these generic drug manufacturers to unilaterally change their label without going through the process proscribed by the FDA and federal law. Federal law prohibits generic manufacturers from changing their drug labels to strengthen safety warnings but the state law claims invoked here would require the manufacturers to change their labels, so the laws are in conflict; it would be impossible for the defendant drug manufacturers to comply with both.[4] Therefore, plaintiffs' claims in counts III through VIII are preempted and must be dismissed.

Missouri Merchandising Practices Act:

The court considers whether plaintiffs can recover under the Missouri Merchandising Practices Act ("MMPA), §§ 407.010 et seq., R.S.Mo. The drug

[4] "Thus, under *Mensing* and *Bartlett*, federal law preempts any state law claim requiring a generic manufacturer to redesign its drug, change its labeling, or leave the market to avoid liability under state law." *Brinkley v. Pfizer, Inc*., 772 F.3d 1133, 1139 (8th Cir. 2014).

manufacturer defendants argue that plaintiffs cannot. The court reaches the opposite conclusion, although the court agrees with the drug manufacturer defendants' argument that plaintiffs have not pled their claim with the requisite specificity.

"The purpose of these [MMPA] statutes is to supplement the definitions of common law fraud in an attempt to preserve fundamental honesty, fair play and right dealings in public transactions." *State ex rel. Danforth v. Indep. Dodge, Inc*., 494 S.W.2d 362, 368 (Mo. App. 1973).

"This act [the MMPA] makes it unlawful to use 'any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce.' § 407.020." *Sunset Pools of St. Louis, Inc. v. Schaefer*, 869 S.W.2d 883, 885 (Mo. Ct. App. 1994). Because plaintiff is alleging fraudulent or deceptive conduct on the part of the seller under the Act, these allegations must be pled with particularity. Rule 55.15.

Medical goods and services meet the statutory definition of "merchandise" as defined by § 407.101(4), R.S.Mo.Medication is "a good," "object," "ware" or "commodity." *Id*. Under the MMPA, a "'private cause of action is given only to one who purchases and suffers damage.' *Jackson v. Charlie's Chevrolet, Inc*., 664 S.W.2d 675, 677 (Mo. App.1 984)." *Freeman Health Sys. v. Wass*, 124 S.W.3d 504, 507 (Mo. App. 2004).

Plaintiffs allege that "Michael Bernstein disbursed significant funds for opioid medications produced, marketed, and sold by [the moving drug manufacturer defendants] and suffered an ascertainable financial loss." SAP, ¶267. Section 407.025.2(c) requires that the individual bringing suit must have "sufficiently definitive and objective evidence to allow the loss to be calculated with a reasonable degree of certainty." However, if a

plaintiff is successful in his MMPA action, he (or she) may recover for actual damages suffered and may also seek punitive damages, attorneys' fees and such other equitable relief as the court may deem proper. *Id.*

However, §407.025.3 specifically excludes actions to recover damages for personal injury or death if such a claim can be made under chapter 538. [5]

The court finds that plaintiffs may maintain a cause of action for a violation of the MMPA, but the allegations must state sufficiently definite and objective evidence which permits his alleged financial losses suffered, as a result of his medication purchases (the dates of which are listed in the SAP)[6], to be calculated with a reasonable degree of certainty. In addition, plaintiffs are required to plead their allegations regarding defendants' deception and falsity with specificity. Currently, plaintiffs' allegations are the sorts of conclusory allegations that are insufficient under the required pleading standard. *Baryo v. Philip Morris USA, Inc*., 435 F. Supp. 2d 961, 968 (W.D. Mo. 2006).

Accordingly, the court grants the drug manufacturer defendants' motion to dismiss the plaintiffs' count XIII of their SAP without prejudice.

Fraudulent Misrepresentation:

Defendants argue that plaintiffs' fraudulent misrepresentation allegations in count XIV are conclusory and not pled with the requisite degree of specificity required. The court agrees. [7] Rule 55.15. While plaintiffs do recite several alleged misrepresentations

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[5] The court notes that, in their Second Amended Petition, under the MMPA count, plaintiffs seek damages for the death and loss of their son pursuant to § 537.080 and § 537.090, R.S.Mo., which are the wrongful death statutes. *See* count XIII, SAP. *Compare* counts I and II, where plaintiffs make such claims. In count I, plaintiffs allege negligence by defendant Polits and seek damages against Polits pursuant to §537.080 and §537.090 R.S.Mo. Count II of plaintiffs' SAP makes the same allegations against defendant Mercy and seeks damages under the same statutes.

[6] See, for example, ¶¶ 51-53 and 67-68 of plaintiffs' SAP.

[7] While condition of mind may be averred generally, parties alleging fraud must plead each essential element. *Arnold v. Erkmann*, 934 S.W.2d 621 (Mo. App. E.D. 1996). The pleader must show a (1) false, material representation, (2) the speaker's knowledge of its falsity or ignorance of its truth, (3) the speaker's intent that

that the defendant drug manufacturers made, they do not allege when these misrepresentations were made, whether the decedent ever came into contact with them, nor whether these misrepresentations were causally related to decedent's death.

WHEREFORE, by reason of the foregoing and the further arguments of the moving drug manufacturer defendants, the court:

1. GRANTS the drug manufacturer defendants' motion to dismiss counts III – VIII of plaintiffs' Second Amended Petition **with prejudice**;
2. GRANTS the drug manufacturer defendants' motion to dismiss counts XIII and XIV of plaintiffs' Second Amended Petition which are directed at them **without prejudice**.

   All other counts to remain pending.

SO ORDERED:

Judge Division 14

Kristine Allen Kerr
Circuit Judge, Division 14

cc: to all parties, through counsel of record, via the court's electronic filing system.

it should be acted upon by the hearer in a manner reasonably contemplated, (4) the hearer's ignorance of the representation's falsity, (5) the hearer's reliance on its truth, (6) the hearer's right to rely thereon, and (7) the hearer's consequent and proximately caused injury. *Id.* Fraud must clearly appear from the allegations of fact and be independent of conclusions. *Id*. Additionally, there must exist a causal connection between the misrepresentation and the damages alleged. *Williams v. Belgrade State Bank*, 953 S.W.2d 187 (Mo. App. S.D. 1997). A claim of fraudulent misrepresentation is subject to the same standard. *Freitas v. Wells Fargo Home Mortg., Inc.,* 703 F.3d 436 (8th Cir. 2013).