[Cite as *Tibbe v. Ranbaxy, Inc.*, 2017-Ohio-1149.]

IN THE COURT OF APPEALS
FIRST APPELLATE DISTRICT OF OHIO
HAMILTON COUNTY, OHIO

ASHLEY N. TIBBE,	:	APPEAL NO. C-16o472 TRIAL NO. A-1405563
and	:	
CHRISTINE TIBBE,	:	*O P I N I O N.*
Plaintiffs-Appellants,	:	
vs.	:	
RANBAXY, INC.,	:	
Defendant-Appellee,	:	
and	:	
RANBAXY LABORATORIES LIMITED, et al.,	:	
Defendants.	:	

Civil Appeal From: Hamilton County Court of Common Pleas

Judgment Appealed From Is: Affirmed

Date of Judgment Entry on Appeal: March 29, 2017

Loeb, Vollman, & Friedmann and *Roger E. Friedmann,* for Plaintiffs-Appellants,

Ulmer & Berne LLP, Thomas G. McIntosh and *Jeffrey F. Peck*, for Defendant-Appellee.

CUNNINGHAM, Judge.

{¶1} Plaintiffs-appellants Ashley and Christine Tibbe appeal the judgment of the common pleas court granting summary judgment to defendant-appellant Ranbaxy, Inc., ("Ranbaxy") on the basis that the Tibbes' claims were preempted by federal law. We affirm the trial court's judgment.

The Tibbes' Claims

{¶2} Ashley Tibbe and her mother, Christine Tibbe, filed a complaint alleging personal injury to Ashley when she was a minor from her ingestion of the drug minocycline, which is the generic form of the brand-name or reference-listed drug ("RLD") Minocin. They alleged that in June 2010, Ashley began using minocycline to treat acne, taking it until September 2011, when she developed lupus as a result of her ingestion of the drug.

{¶3} The Tibbes further alleged that the generic form of minocycline that Ashley had ingested had been manufactured by several companies, including Ranbaxy,[1] and that Kroger Limited Partnership I ("Kroger") had operated the pharmacies that filled the prescriptions for minocycline and dispensed or supplied the generic form of the drug. They also alleged that Christine had incurred and paid certain medical expenses and other expenses related to Ashley's care and treatment, and that she had also suffered emotional distress and anxiety related to Ashley's injuries.

{¶4} The Tibbes' complaint included causes of action against Ranbaxy and Kroger in products-liability negligence, common-law fraud and misrepresentation, Ohio Consumer Sales Practices Act violations, and negligent failure to counsel. The

[1] The Tibbes voluntarily dismissed their claims against defendants Teva Pharmaceuticals USA, Inc., and Actavis, Inc., f.k.a. Watson Pharmaceuticals, Inc., prior to the trial court's ruling on their motions to dismiss.

gravamen of the claims was that the defendants had failed to adequately warn "the plaintiffs and others," including physicians, of the risks associated with the use of minocycline, particularly the risk of developing lupus, in violation of state law. The Tibbes further alleged that the defendants had violated federal law by failing to report adverse events to the Food and Drug Administration ("FDA") and by "fail[ing] to follow FDA procedures concerning product letters of approval."

{¶5} Kroger filed an answer and a cross-claim against Ranbaxy seeking indemnification and contribution for any judgment that might be rendered against it. Kroger also filed a "counterclaim" against Christine Tibbe. Kroger alleged that "its actions or omissions, if any, were passive, remote, and secondary to the active and primary negligence of Christine Tibbe" and that it was entitled to contribution and indemnification from Christine Tibbe in the event any liability was assessed against it.

Ranbaxy's and Kroger's Motions to Dismiss

{¶6} Ranbaxy and Kroger each filed motions to dismiss the Tibbes' complaint. They argued that the Tibbes' claims were predicated upon a failure-to-warn theory and that under the United States Supreme Court's decision in *Pliva, Inc. v. Mensing*, 564 U.S. 604, 609, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011), such state-law failure-to-warn claims against generic-drug manufacturers and suppliers were preempted by federal law because it was impossible for them to comply with their state-law duty to adequately warn and their federal-law duty to maintain the same labeling as their brand-name counterpart. They additionally argued that the Tibbes' allegations that the defendants had violated federal law by failing to report adverse events to the FDA and by failing to "follow FDA product letters of approval" failed to assert a state-law claim because there is no private right to enforce the federal Food

Drug and Cosmetic Act's [FDCA] provisions. *See* 21 U.S.C. 337(a) ("proceedings for enforcement of the FDCA shall be by and in the name of the United States"); *see also Buckman v. Plaintiff's Legal Comm.*, 531 U.S. 341, 349, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), fn. 4 ("The FDCA leaves no doubt that it is the Federal Government rather than litigants who [is] authorized to file suit for noncompliance with the FDCA.").

{¶7} In their memorandum opposing the motions, the Tibbes argued that they may have a claim that fit within what they characterized as a "narrow exception" to preemption based on the "failure-to-update theory" articulated by the Sixth Circuit in *Fulgenzi v. Pliva*, 711 F.3d 578 (6th Cir.2013). The Tibbes contended, however, that without discovery, they could not assert a failure-to-update claim against Ranbaxy. Likewise, the defendants could not demonstrate that their labeling was the same as the RLD, Minocin, as required for preemption under *Mensing*. The Tibbes additionally argued for the first time that the defendants should have accompanied their minocycline products with a warning to consumers that they have no "recourse for any harm that may be caused by their drugs."

{¶8} The trial court denied the defendants' motions to dismiss. In its entry, the trial court acknowledged the preemptive effect of federal law on the Tibbes' claims, but found, citing *Fulgenzi,* that there was an "exception" to federal preemption for a claim based on a failure-to-update theory. The trial court concluded that Ranbaxy and Kroger "[could] not prove that they were unequivocally entitled to federal preemption at this time" and permitted the Tibbes to conduct "discovery to determine the facts that would support their claims against both Ranbaxy and Kroger."

Ranbaxy's Motion for Summary Judgment

{¶9} Following discovery, Ranbaxy moved for summary judgment on the basis that the "*Fulgenzi* exception" as articulated in the trial court's entry did not apply and that the Tibbes' claims were, therefore, preempted under *Mensing*, 564 U.S. 604, 131 S.Ct. 2567, 180 L.Ed.2d 580. In *Fulgenzi*, the Sixth Circuit held that a plaintiff's state-law failure-to-warn claim against a generic-drug manufacturer was not preempted by federal law where the plaintiff had alleged that the generic manufacturer had failed to update its labeling to match the updated labeling of the brand-name manufacturer. *See Fulgenzi* at 585.

{¶10} The Sixth Circuit reasoned that because the generic manufacturer could have independently updated its labeling to match that of the brand-name manufacturer, and, in fact, had a federal duty to do so, compliance with both federal and state-law duties was not just possible, it was required. *Id*. Thus, it held that the plaintiff's narrow argument that the generic manufacturer's warning was inadequate to the extent that it did not include language contained in the updated brand-name label was not preempted under *Mensing*. *Id*.

{¶11} Ranbaxy pointed out that the FDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *See* 21 U.S.C. 321(m). The FDA regulations define "[l]abeling [to] include all written, printed, or graphic matter accompanying any article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce"; and "label means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or

affixed to or appearing upon a package containing any consumer commodity." *See* 21 C.F.R. 1.3.

{¶12} Ranbaxy argued that the pharmacy records produced by Kroger showed that Ashley had received prescriptions of Ranbaxy's generic minocycline from June 2010 to August 2011. During that time, the warning language for lupus in Ranbaxy's generic minocycline package insert matched the warning language for lupus in the package insert for the RLD, Minocin.

{¶13} Ranbaxy attached to its motion for summary judgment Ashley's pharmacy records, as well as the package inserts from the RLD, Minocin, and the generic minocycline manufactured by Ranbaxy for the time period that Ashley had allegedly consumed the drug. Ranbaxy, citing federal case law, argued that the trial court could take judicial notice of the package insert for Minocin as set forth on the FDA website. Ranbaxy also attached the affidavit of Usha Sankaran, the senior director of regulatory affairs, North America, for Ranbaxy.

{¶14} Sankaran averred that Ranbaxy had submitted its abbreviated new drug application ("ANDA") of 100 mg minocycline hydrochloride for FDA approval on December 27, 1999. The FDA had approved the ANDA on November 30, 2000. The package insert for Ranbaxy's generic 100 mg minocycline hydrochloride in effect in June 2010 has a revision date of January 2009 and went into effect in May 2009. The package insert for Ranbaxy's generic 100 mg minocycline hydrochloride in effect in April 2011 has a revision date of February 2011 and went into effect in April 2011. There were no other package inserts in effect for Ranbaxy's generic 100 mg minocycline hydrochloride between June 2010 and April 2011.

{¶15} Sankaran further averred that the package inserts for Ranbaxy's 100 mg generic minocycline hydrochloride and the RLD, Minocin, contained the same warning relating to lupus under the adverse reactions section:

> Hypersensitivity reactions; Urticaria, angioneurotic edema, polyarthralgia, anaphylaxis/anaphylactoid reaction (including shock and fatalities), anaphylactoid purpura, myocarditisi, pericarditis, exacerbation of systemic lupus erythemaosus and pulmonary infiltrates with eosinophilia have been reported. A transient lupus-like syndrome and serum sickness-likeness reactions also have been reported.
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> * * *
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> Lupus-like syndrome consisting of positive antinuclear antibody; arthralgia; arthritis, joint stiffness, or joint swelling; and one or more of the following: fever, myalgia, hepatitis, rash and vasculitis.

{¶16} In their memorandum opposing summary judgment, the Tibbes argued that Ranbaxy had failed to meet its burden of proof because Sankaran's statement, by itself, that the labels for its generic minocycline and the RLD, Minocin, were identical was insufficient to support summary judgment where the affidavit referred to the attached package inserts for minocycline only. They additionally argued that summary judgment was improper because Ranbaxy had failed to warn that it had no duty as a generic manufacturer to independently verify the warnings on its labels. They asserted that such a warning would not be preempted under *Mensing*, because it did not imply any type of therapeutic difference between the generic minocyline and the RLD, Minocin. The Tibbes argued that because Ranbaxy

had not addressed this argument in its motion for summary judgment, the trial court could not grant it summary judgment on this claim.

{¶17} After the trial court took judicial notice of the package inserts for the RLD, Minocin, it granted summary judgment to Ranbaxy on the basis that the Tibbes' claims were preempted by federal law. The trial court stated that the "exception" to federal preemption articulated in *Fulgenzi* did not apply because Ranbaxy had presented admissible evidence that the warning language for lupus on Ranbaxy's minocycline label was the same as the warning language on the RLD, Minocin, label. Thus, under *Mensing*, any claim that Ranbaxy should have added additional warnings to its labeling would be preempted by federal law.

{¶18} The Tibbes appealed the trial court's order. Ranbaxy filed a motion to dismiss the Tibbes' appeal. It argued that because the trial court's entry granting summary judgment lacked Civ.R. 54(B) certification, and the Tibbes' claims against Kroger remained pending in the trial court, the entry was not a final appealable order. We agreed and dismissed the Tibbes' appeal.

{¶19} Shortly thereafter, the Tibbes voluntarily dismissed their claims against Kroger without prejudice pursuant to Civ.R. 41(A)(1)(a). The Tibbes then filed another notice of appeal from the trial court's order granting summary judgment to Ranbaxy.

Jurisdiction

{¶20} As an initial matter, we note that the Tibbes' voluntary dismissal of their claims against Kroger created a final appealable order. Civ.R. 41(A)(1)(a) provides that:

> [A] plaintiff, without order of court, may dismiss all claims asserted by that plaintiff against a defendant by doing either of the

> following: (a) filing a notice of dismissal at any time before the commencement of trial unless a counterclaim which cannot remain pending for independent adjudication by the court has been served by that defendant[.]

{¶21} While the record reflects that Kroger filed a purported "counterclaim" against Christine Tibbe, this claim was in effect a cross-claim because it was dependent upon a finding of liability against Kroger. Because the Tibbes' dismissal of their claims against Kroger precludes a finding of liability against it, Kroger's claim against Christine Tibbe is moot. *See Wise v. Gursky*, 66 Ohio St.2d 241, 243, 421 N.E.2d 150 (1981); *Wisintainer v. Elcen Power Strut Co.*, 67 Ohio St.3d 352, 355, 617 N.E.2d 1136 (1993); *see also Unternaher v. Heath*, 5th Dist. Licking No. 14-CA-108, 2015-Ohio-3069, ¶ 20. Thus, the trial court's order granting summary judgment to Ranbaxy is a final appealable order.

Summary Judgment

{¶22} In their sole assignment of error, the Tibbes argue the trial court erred by granting summary judgment in favor of Ranbaxy on the basis that their state-law claims were preempted by federal law.

{¶23} We review the grant of summary judgment de novo, employing the same standard as the trial court. Summary judgment is appropriate where there is no genuine issue of material fact, the moving party is entitled to judgment as a matter of law, and the evidence demonstrates that reasonable minds can come to but one conclusion, and that conclusion is adverse to the party opposing the motion. *Comer v. Risko*, 106 Ohio St.3d 185, 2005-Ohio-4559, 833 N.E.2d 712, ¶ 8.

Federal Regulation of Pharmaceutical Drugs

{¶24} The marketing of pharmaceutical drugs is heavily regulated by federal law. The FDA is the federal agency charged by Congress with regulating the manufacture, sale, and labeling of new prescription drugs. *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litigation*, 756 F.3d 917, 922 (6th Cir.2014). To acquire federal approval to market a drug, the 1962 Drug Amendments to the FDCA require that a manufacturer prove that the proposed drug is "safe and effective and that the proposed label is accurate and adequate," which occurs by way of lengthy and costly clinical testing. *Id*. For a period of time, all manufacturers had to complete the same approval process, regardless of whether the manufacturer was seeking to market an entirely new pharmaceutical drug or merely a new generic version of an existing drug. *Id*.

{¶25} Congress, however, in the 1984 Drug Price Competition and Patent Term Restoration Act, popularly known as the Hatch-Waxman Amendments to the FDCA, in an effort to increase the availability of low-cost generic drugs, altered the approval process for generic drugs. The Hatch-Waxman Amendments permit manufacturers to obtain expedited FDA approval of a generic version of a drug where the active ingredients of the generic drug are the same as the RLD—generally a brand-name drug that has already been approved by the FDA—and the safety and efficacy of the labeling proposed is the same as the labeling approved for the RLD. *Id*. at 923.

{¶26} The FDA has created procedures by which manufacturers can make changes to a drug's approved labeling. Brand-name manufacturers may seek to modify a drug's labeling through a "Prior Approval Supplement," which requires submission to and approval by the FDA prior to distribution of the product, or

through a "changes-being-effected" (CBE) supplement, which must be submitted 30 days before distribution, but does not require prior FDA approval. Label changes to add or strengthen a contradiction, warning, precaution, or adverse reaction, may be made through the CBE process. *Id*.

{¶27} In *Mensing*, 564 U.S. 604, 131 S.Ct. 2567, 180 L.Ed.2d 580, the United States Supreme Court recognized that under federal regulations, generic manufacturers have different labeling responsibilities from their brand-name counterparts. In *Mensing*, the plaintiffs had argued that they had developed tardive dyskinesia based on their long term use of the generic drug metoclopramide and that the generic manufacturers were liable under state law for failing to provide adequate warnings of the risk or prevalence of tardive dyskinesia. *Id*. at 610. The generic manufacturers argued that the failure-to-warn claims were preempted because they, as generic manufacturers, could not unilaterally change their labels after their initial FDA approval to include warnings that varied from Reglan, the brand name or RLD. *Id*.

{¶28} The Supreme Court agreed with the generic manufacturers. It held that because generic manufacturers were required under federal law to maintain the same labeling as the brand-name drug Reglan, to the extent state law would have required the generic manufacturers to use a stronger warning label state and federal law conflicted, making it impossible for the generic manufacturers to comply with both laws. The Supreme Court held that federal law, therefore, preempted state law on plaintiffs' failure-to-warn claim. *Id*. at 613.

{¶29} The Supreme Court rejected the plaintiffs' arguments that the generic manufacturers could have utilized the FDA's "changes-being-effected" process

and/or "dear doctor" letters to unilaterally strengthen their warning labels without waiting for FDA approval. *Id*. at 614-615.

{¶30} The *Mensing* court stated that the possibility of complying with both state and federal law did not defeat a finding of conflict preemption. It held that the federal duty to seek a labeling change from the FDA would not have satisfied the state-law duty to warn, and the manufacturers were not required to prove that they would have been prohibited from making a labeling change if they had asked the FDA for permission to do so in order to establish conflict preemption. The court explained:

> This raises the novel question whether conflict pre-emption should take into account these possible actions by the FDA and the brand-name manufacturer. Here, what federal law permitted the manufacturers to do could have changed, even absent a change in the law itself, depending on the actions of the FDA and the brand-name manufacturer. Federal law does not dictate the text of each generic drug's label, but rather ties those labels to their brand-name counterparts. Thus, federal law would permit the generic manufacturers to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so.

Id. at 620.

{¶31} The *Mensing* plaintiffs had additionally argued that the manufacturers could not establish conflict preemption because they had not tried to start the process for seeking a label change with the FDA and the brand-name manufacturer. The court rejected this "fair argument" stating

> the question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it. Accepting [plaintiffs'] argument would render conflict pre-emption largely meaningless because it would make most conflict between state and federal law illusory.

[Citations omitted.] *Id*. Thus, the court found that conflict preemption had been established. The court stated

> 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 duties for pre-emption purposes.

Id. at 623-624.

{¶32} The *Mensing* court recognized the unfortunate hand that federal drug regulation had dealt plaintiffs who have consumed generic drugs. The court recognized that had the plaintiffs consumed the brand-name drug prescribed by their doctors, instead of the generic version, their lawsuits would not be preempted by federal law. The *Mensing* court held, however, that it was not "its task to decide whether the statutory scheme established by Congress is unusual or even bizarre" and that it would "not distort the Supremacy clause in order to create similar preemption across a dissimilar statutory scheme." *Id*. at 625. Thus, the *Mensing* court concluded that Congress and the FDA retained the authority to change the law and regulations if they desired. *Id*.

{¶33} In *Stayhorn v. Wyeth Pharms, Inc.*, 737 F.3d 378, 391 (6th Cir.2013), the Sixth Circuit rejected plaintiffs' argument that *Mensing* should be read narrowly

to preempt only those state-law claims based on the adequacy of the information contained in the drug's label and not claims based on "a manufacturer's duty to provide a warning beyond the label." The Sixth Circuit noted that such a narrow reading of *Mensing* had been "soundly rejected by all circuits to consider [it]." *Id*. The court noted that the "circuits had interpreted *Mensing* to broadly preempt claims that are, at their core, claims that the generic manufacturers failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturer." *Id*. at 391.

Summary Judgment was Properly Granted to Ranbaxy

{¶34} In its motion for summary judgment, Ranbaxy argued that the Tibbes' claims were preempted under *Mensing* because the package inserts for the brand-name drug Minocin and its generic drug, minocycline, were identical, containing the same warning language related to lupus at the time that Ashley had been prescribed minocycline. In their appellate brief, the Tibbes do not dispute that Ranbaxy has a federal-law duty as a generic manufacturer to maintain the same labeling as the brand-name manufacturer. Nor do the Tibbes dispute the sameness of the labeling for Ranbaxy's generic minocycline and the brand-name RLD, Minocin, during the time that Ashley had consumed Ranbaxy's generic minocycline.

{¶35} Instead, they argue that the trial court erred in granting summary judgment to Ranbaxy because there is a genuine issue of material fact as to whether Ranbaxy had an additional duty to warn consumers of the generic version of the drug that they cannot bring a state-law failure-to-warn claim when their prescriptions are filled with Ranbaxy's generic minocycline and the labeling for the drug is the same as that of the RLD. The Tibbes argue that "Ranbaxy knows under the current landscape that they can escape liability for any deficiencies in their product by simply

maintaining the same warnings that the brand-name drug equivalent uses, yet they do not warn consumers that they are not liable for any deficiencies in their labels, and they failed to take precautions that a reasonable company would take in presenting this information to the consumer."

{¶36} The Tibbes argue that they were unaware that by purchasing the Ranbaxy product, they would be forfeiting their right to contest the adequacy of the warning labels that accompanied Ashley's prescription, and that they accepted this risk without ever knowing about it. As a result, they assert that Ranbaxy has violated its state-law duty to warn consumers that once they purchase a generic version of the drug, they have no right to sue the generic manufacturer if its labeling is the same as that of the brand-name manufacturer.

{¶37} While the trial court did not directly address this argument on summary judgment, we cannot conclude the trial court erred in granting summary judgment to Ranbaxy on the Tibbes' failure-to-warn claims, including this particular one. We need not determine whether the Tibbes' claim that Ranbaxy must warn consumers they cannot prosecute a state-law failure-to-warn claim when its labeling matches that of the brand-name manufacturer would be preempted by federal law.

{¶38} As Ranbaxy points out, the Tibbes did not plead this specific failure-to-warn claim in their complaint and they cite no law to support their argument. Under the Ohio Product Liability Act, a manufacturer, such as Ranbaxy, has a duty to warn of the risks associated with the product. *See* R.C. 2307.76(A)(1)(a). There is no corresponding duty to warn a consumer of her legal rights or the prospective outcome of litigation should she decide to sue a drug manufacturer at a future point in time. Thus, a claim based on that theory would not be available under Ohio law. *See* R.C. 2307.71(B) ("Sections R.C. 2307.71 to 2307.80 of the Revised Code are

intended to abrogate all common law product liability claims or causes of action."). Similarly, the Tibbes could not pursue this claim under the Ohio Consumer Sales Practices Act because the Act does not apply to claims for personal injuries. *See* R.C. 1345.12(C).

{¶39} Because there are no genuine issues of material fact and Ranbaxy is entitled to judgment as a matter of law, the trial court did not err in granting summary judgment to Ranbaxy on the basis that the Tibbes' claims that Ranbaxy had failed to adequately warn the plaintiffs and others, including physicians, of the risks of injury associated with the use of minocycline, particularly the risk of developing lupus, were preempted by federal law. Similarly, the trial court did not err in granting summary judgment to Ranbaxy on the Tibbes' claim that Ranbaxy, as a generic manufacturer, had a state-law duty to warn consumers regarding their potential legal rights, because their claim is not supported by Ohio law. We, therefore, overrule the sole assignment of error and affirm the judgment of the trial court.

Judgment affirmed.

MOCK, P.J., and **ZAYAS, J.,** concur.

Please note:

The court has recorded its own entry this date.