

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
AUSTIN DIVISION

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CLERK US DISTRICT COURT  
WESTERN DISTRICT OF TEXAS  
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DEPUTY

JEAN MASSEY AND MICHAEL MASSEY, §  
PLAINTIFFS, §  
§  
V. §  
NOVARTIS PHARMACEUTICALS §  
CORPORATION, §  
DEFENDANT. §

A-12-CV-1054-LY

**ORDER**

Before the court are Defendant Novartis Pharmaceuticals Corporation’s Motion for Summary Judgment in the *Massey* Case filed February 21, 2014 (Doc. #95); Plaintiffs’ Response in Opposition to Defendant’s Motion for Summary Judgment filed March 7, 2014 (Doc. #101); Novartis Pharmaceuticals Corporation’s Reply in Support of its Motion for Summary Judgment filed March 21, 2014 (Doc. #107); Defendant Novartis Pharmaceuticals Corporations’s Supplemental Brief Concerning *McKay v. NPC* filed June 4, 2014 (Doc. #122); Plaintiff’s Response to Defendant’s Supplemental Brief Concerning *McKay v. NPC* filed June 6, 2014 (Doc. #123); and Defendant Novartis Pharmaceuticals Corporation’s Brief in Support of its Supplemental Brief Concerning *McKay v. NPC* filed June 12, 2014 (Doc. #124).

Also before the court are Defendant Novartis Pharmaceuticals Corporation’s *Daubert* Motion to Exclude Specific Causation Testimony of Plaintiff’s Expert Witness filed February 21, 2014 (Doc. #97); Plaintiffs’ Response in Opposition to Novartis Pharmaceuticals Corporation’s *Daubert* Motion to Exclude Specific Causation Testimony of Plaintiff’s Expert Witnesses filed March 7, 2014 (Doc. #99); and Novartis Pharmaceuticals Corporation’s Reply in Support of its Motion to Exclude

Causation Testimony of Plaintiff's Retained Expert and Non-Retained Treating Physicians filed March 20, 2014 (Doc. #106).

The court held a hearing on the motions on May 1, 2014. Having considered the motions, responses, replies, supporting evidence, the argument of counsel, and the applicable law, the court will grant the summary-judgment motion and dismiss all of Plaintiffs' claims and dismiss all other pending motions for the reasons to follow.

### **I. BACKGROUND**

Plaintiff Jean Massey was diagnosed with metastatic breast cancer in August of 2005. Her treatment included monthly doses of Zometa, a biophosphonate used to treat bone metastasis. In June 2006, Massey developed osteonecrosis of the jaw, a painful condition that forced her to limit her diet to soft foods. Massey's cancer metastasized to her brain in April 2007, and she died shortly thereafter. Before she died, Massey and her husband Michael filed suit against Defendant Novartis Pharmaceuticals Corporation ("Novartis"), the manufacturer of Zometa, in the United States District Court for the District of Columbia, asserting six causes of action: (1) strict liability, (2) negligent manufacture, (3) negligent failure to warn, (4) breach of express warranty, (5) breach of implied warranty, and (6) loss of consortium. After Jean Massey died, Michael Massey ("Massey") continued the lawsuit as plaintiff and executor of his wife's estate.

The Judicial Panel on Multidistrict Litigation transferred this case to a Multidistrict Litigation Court in the Middle District of Tennessee (the "MDL court"). Novartis moved for partial summary judgment before the MDL court on all claims in several cases, including Massey's, that alleged failure by Novartis to provide adequate warnings or information about Zometa. Novartis asserted

in the MDL court that it was entitled to summary judgment based on the Texas Civil Practice and Remedies Code and federal preemption principles.

The MDL applied Texas law. *See In re Aredia & Zometa Products Liab. Litig.*, 3:06-MD-1760, 2008 WL 2944910 (M.D. Tenn. July 25, 2008).<sup>1</sup> Texas law presumes a defendant is not liable for failure to warn, if the drugs were accompanied by an FDA-approved label. *See* TEX. CIV. PRAC. & REM. CODE §82.007(a) (West 2011). But the presumption may be rebutted if, *inter alia*, “the defendant, before or after pre-market approval of licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant’s injury.” *Id.* at §82.007(b)(1). Before the MDL court, Massey asserted this fraud-on-the-FDA rebuttal. The court, however, held that the fraud-on-the-FDA rebuttal was preempted by the statutory scheme employed by the federal Food, Drug, and Cosmetic Act, granted Novartis’s motion for partial summary judgment, and dismissed Massey’s failure-to-warn claims. *In re Aredia & Zometa Products Liab. Litig.*, 2008 WL 2944910 at \*4-5 (citing *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001)). The MDL court returned the case to the United States District Court for the District of Columbia, after which the parties stipulated the transfer the case to the this court.

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<sup>1</sup> Massey was not a party to the MDL court’s July 25, 2008 order. The MDL court dismissed Massey’s failure-to-provide-adequate-warnings-or-information claims in a subsequent order that incorporated the reasons set forth in its July 25, 2008 order. *See* Order Granting Partial Summary Judgment for Defendant Novartis Pharmaceuticals Corporation, *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760 (M.D. Tenn. Nov. 24, 2008).

## II. ANALYSIS

### ***Summary-judgment Standard***

Summary judgment shall be rendered when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986); *Ragas v. Tenn. Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998). If the moving party carries its burden of showing that there is no genuine dispute as to any material fact, the burden shifts to the nonmovant to introduce specific facts or produce evidence that shows the existence of a genuine dispute regarding a material fact that prevents the grant of summary judgment in the movant’s favor. FED. R. CIV. P. 56(e); *see also Celotex*, 477 U.S. at 322–23. A dispute regarding a material fact is genuine if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). This court views the evidence in the light most favorable to the nonmovant, drawing all reasonable inferences in the nonmovant’s favor. *Allen v. McWane, Inc.*, 593 F.3d 449, 452 (5th Cir. 2010). Further, a court “may not make credibility determinations or weigh the evidence” in ruling on a motion for summary judgment. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *Anderson*, 477 U.S. at 25-55.

### ***Law-of-the-case Doctrine***

The existence of a prior ruling invokes the law-of-the-case doctrine, which provides that settled issues will not be revisited during the pendency of a lawsuit. *See In re Ford Motor Co.*, 591 F. 3d 406 (5th Cir. 2009). The law-of-the-case doctrine applies equally where the prior ruling was made by an MDL court:

In reviewing transferee court decisions under the law of the case doctrine, transferor courts should rarely reverse, because any widespread overturning of transferee court decisions would frustrate the principle aims of the MDL process and lessen the system's effectiveness. The law of the case doctrine "requires attention to the special authority granted to the multidistrict transferee judge" and ensures that transferor courts respect the transferee court's decisions. That doctrine also has the virtue of allowing transferor courts to correct serious errors of the transferee court.

*Id.* at 411 (internal citation omitted).

Like Massey, the plaintiffs in *McKay v. Novartis Pharmaceutical Corp.*, 751 F.3d 694 (5th Cir. 2014), filed suit against Novartis alleging claims for strict liability, negligence, and breach of warranties. The case was transferred to the Middle District of Tennessee MDL court, which granted partial summary judgment in favor of Novartis. *Id.* at 697. On remand, the district court granted summary judgment against the plaintiffs on their remaining claims, finding that the MDL court's ruling that Section 82.007(a)'s presumption against liability precluded all of the plaintiffs' claims premised on Novartis's failure to warn. *Id.* On appeal, the plaintiffs argued that the remand court erred by refusing to consider two new arguments raised before that court regarding the presumption. *Id.* at 703. The Fifth Circuit held that "the remand court properly applied the law of the case when it refused to reconsider the MDL court's rulings that §82.007 applied to the McKays' failure to warn claims." *Id.* at 705. Likewise, this court will not disturb the MDL court's ruling that the presumption applies and will instead determine whether Massey's remaining claims are premised on failure to warn.

### ***Strict-Liability and Negligent-Manufacture Claims***

"Texas, like most jurisdictions, has adopted section 402A of the Restatement of Torts for product liability claims." *McNeil v. Wyeth*, 462 F. 3d 364, 368 (5th Cir. 2006) (citing *Nobility Homes, Inc. v. Shivers*, 557 S.W.2d 77, 79-80 (Tex.1977)). Comment k of section 402A provides

that there are some products cannot be made safe in their normal and intended use, but that this inherent dangerousness does not give rise to strict liability where the product is accompanied by an adequate warning. REST. 2D TORTS, § 402A, cmt. k (1965). Thus, under Texas law, Novartis can be held strictly liable only if Zometa was not properly prepared or marketed or accompanied by proper warnings. *See id.* *See also Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1274-75 (5th Cir. 1974). The court finds that Massey's strict-liability claim is premised on Novartis's alleged failure to warn and therefore concludes Novartis is entitled to summary judgment.

The court also finds Massey's negligent-manufacture claim is premised on the alleged inadequacy of Zometa's warning. Massey alleges a failure to properly test Zometa. In *Skotak v. Tenneco Resins, Inc.*, 953 F. 2d 909, 912 (5th Cir. 1992), the Fifth Circuit expressly held that a plaintiff alleging negligence claims has the burden to show that the warning accompanying the drug is both inadequate and a producing cause of the injury. In light of the MDL court's ruling, however, Massey cannot show that Zometa's warnings were inadequate under *Skotak*. Therefore, Novartis is entitled to summary judgment on Massey's negligent-manufacture claim.

### ***Warranty Claims***

Massey's remaining claims for breach of express warranty, breach of implied warranty, and loss of consortium also fail. As to the warranty claims, the court finds that Massey did not provide Novartis with the required presuit notice. Texas law requires that "the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." TEX. BUS. & COM. CODE § 2.607(c)(1). Massey argues that Novartis had notice because Novartis received several Adverse Event reports from other claimants. Under Texas law, such generalized notice is not sufficient to satisfy the notice requirement: "The

manufacturer must be made aware of a problem with a particular product purchased by a particular buyer.” *U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194, 201-02 (Tex. App.– Houston [1st Dist.] 2003, pet. denied). Therefore, Novartis is entitled to judgment on Massey’s warranty claims.

Having determined that Novartis is entitled to summary judgment on all of Massey’s direct claims, the court will dismiss Massey’s remaining derivative loss-of-consortium claim.

### III. CONCLUSION

**IT IS THEREFORE ORDERED** that Defendants’ Motion for Summary Judgment on All Claims (Doc. #95) is **GRANTED**.<sup>2</sup> All of Plaintiffs’ claims are **DISMISSED WITH PREJUDICE**.

A final judgment shall be rendered subsequently.

SIGNED this 19th day of September, 2014.

  
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LEE YEAKEL  
UNITED STATES DISTRICT JUDGE

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<sup>2</sup> Having granted summary judgment in favor of Novartis, the court need not address Novartis’ *Daubert* motion. Accordingly, it is **ORDERED** that Defendant Novartis Pharmaceuticals Corporation’s *Daubert* Motion to Exclude Specific Causation Testimony of Plaintiff’s Expert Witness filed February 21, 2014 (Doc. #97) is **DISMISSED**.