

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

IN RE:	)
AREDIA and ZOMETA PRODUCTS	)
LIABILITY LITIGATION	) NO. 3-06-MD-1760
	) JUDGE CAMPBELL
This Document Relates To Case Number:	)
3:08-0913 (Eberhart)	)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 3476).

For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part.

FACTS

Plaintiff has brought this action against Defendant Novartis, alleging that Defendant's drugs Aredia and Zometa caused her to develop osteonecrosis of the jaw ("ONJ"). Plaintiff asserts claims for strict liability, negligence, and negligence *per se* in connection with the design and labeling (i.e., failure to warn) of Aredia and Zometa. Docket No. 3571, p. 22. Defendant has moved for summary judgment on all of Plaintiff's claims.

SUMMARY JUDGMENT

Summary judgment is appropriate where there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Pennington v. State Farm Mut. Automobile Ins. Co.*, 553 F.3d 447, 450 (6th Cir. 2009). The party bringing the summary judgment motion has the initial burden of informing the Court of the basis for its motion and identifying portions of the record that demonstrate the absence of a genuine dispute over material facts. *Rodgers v. Banks*, 344 F.3d 587, 595 (6th Cir. 2003). The moving party may satisfy this

burden by presenting affirmative evidence that negates an element of the non-moving party's claim or by demonstrating an absence of evidence to support the nonmoving party's case. *Id.*

In deciding a motion for summary judgment, the Court must review all the evidence, facts and inferences in the light most favorable to the nonmoving party. *Pennington*, 553 F.3d at 450; *Van Gorder v. Grand Trunk Western Railroad, Inc.*, 509 F.3d 265, 268 (6th Cir. 2007). The mere existence of a scintilla of evidence in support of the nonmoving party's position will be insufficient to survive summary judgment; rather, there must be evidence on which the jury could reasonably find for the nonmoving party. *Rodgers*, 344 F.3d at 595 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986)).

#### CAUSATION

Defendant contends that Plaintiff is unable to establish specific causation<sup>1</sup> in this case because her designated experts fail to meet the criteria for admissible expert testimony. The Court has denied Defendant's Motion to Exclude the testimony of Dr. Robert Kraut, who opined that Ms. Eberhart's failure to heal following her tooth extractions was caused by the presence of bisphosphonate in her jaw bone, secondary to her Aredia and Zometa therapy.

Defendant argues that Plaintiff's expert witnesses have not offered a specific causation opinion to a degree of reasonable medical probability or reasonable certainty. In Georgia, where issues of causation can be resolved solely by expert medical evidence, that evidence must naturally be based at least on reasonable probability. *Allison v. McGhan Medical Corp.*, 184 F.3d 1300, 1320 (11th Cir. 1999). The standard of proof in a civil case is preponderance of the evidence, and

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<sup>1</sup> This Court has previously ruled that there are genuine issues of material fact as to whether Aredia and Zometa generally cause ONJ, and that ruling applies here.

reasonable medical probability is the functional equivalent of preponderance of the evidence. *Id.*; *see also Estate of Patterson v. Fulton-DeKalb Hosp. Authority*, 505 S.E.2d 232, 234 (Ga. Ct. App. 1998) (reasonable medical probability has no greater meaning than preponderance of the evidence as to medical causation) and *Ambling Mgmt. Co. v. Purdy*, 640 S.E.2d 620, 627 (Ga. Ct. App. 2006) (Georgia case law requires only that an expert state an opinion regarding proximate causation in terms stronger than that of medical possibility).

Dr. Kraut stated: “It is my considered opinion that the failure to heal following these extractions was caused by the presence of bisphosphonate in her jaw bone secondary to her therapy with initially Aredia and subsequently Zometa.” Docket No. 3450-41. He concluded by finding “an unquestionable diagnosis of Stage II bisphosphonate induced jaw necrosis based on current AAOMS standards.” *Id.* The Court finds, for purposes of summary judgment, Dr. Kraut’s testimony is sufficient to meet the preponderance of the evidence/reasonable probability standard.

For all these reasons, the Court finds that Plaintiff has sufficiently demonstrated a genuine issue of material fact as to specific causation, and Defendant’s Motion for Summary Judgment on this issue is denied.

#### FAILURE TO WARN

Under Georgia law, to establish a products liability claim for failure to warn, Plaintiff must show that the Defendant had a duty to warn, that Defendant breached that duty, and that the breach proximately caused the Plaintiff’s injury. *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010). Within the context of prescription drugs, the manufacturer has a duty to warn the patient’s doctor, who acts as a learned intermediary between the patient and the manufacturer. *Id.*

This Court has already found that there are genuine issues of material fact as to whether Defendant's warnings were adequate and timely, and that ruling applies here. Defendant argues, however, that Ms. Eberhart cannot establish that an alleged inadequate warning caused her ONJ. A plaintiff must demonstrate that the deficient warning proximately caused her alleged injury to prevail. *Dietz*, 598 F.3d at 816. If the learned intermediary would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the causal link is broken and the plaintiff cannot recover. *Id.*

Citing the undisputed testimony of Ms. Eberhart's oncologist, Defendant asserts that, even knowing what she knows now, Dr. Galleshaw would have recommended that Ms. Eberhart "embark on bisphosphonate therapy" in 2001. Docket No. 3479-38, p. 9 (p. 50 of Dr. Galleshaw's deposition); *see also* Docket No. 3561, ¶ 36.

Dr. Galleshaw also testified, however, that once she became aware of the potential link between bisphosphonates and ONJ, she met with her partners and discussed the possible connection in December 2004. Docket No. 3578-5,<sup>2</sup> p.9 (deposition, p. 21). She and her fellow doctors now provide patients with a specific handout describing side effects of the drug before starting the patients on Zometa. *Id.*, pp. 14-15 (deposition, pp. 31-32). That handout includes, among other things, a warning that invasive dental procedures should be avoided during treatment. *Id.*, p. 23 (deposition, p. 85). Dr. Galleshaw testified that if she is about to initiate a bisphosphonate, she does not just give the patient this handout; she actually has a discussion about it and asks questions about the patient's dental care. *Id.*

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<sup>2</sup> Plaintiff's cited excerpts from Dr. Galleshaw's deposition are not identified on the Docket Sheet for this action. The Court was able to find them, however, as Exhibit 5 to Docket No. 3561 by reviewing the Notice of Filing.

Clearly, even if Dr. Galleshaw had recommended that Ms. Eberhart be given Zometa, Dr. Galleshaw would take a different course of conduct prior to starting Ms. Eberhart on the drug, giving Ms. Eberhart a more informed choice concerning the risks. Plaintiff has presented evidence which is sufficient to demonstrate a genuine issue of material fact as to causation, and Defendant's Motion for Summary Judgment on this issue is denied.

#### NEGLIGENCE *PER SE*

Plaintiff asserts that Novartis is guilty of negligence *per se* based upon alleged violations of the Federal Food, Drug and Cosmetic Act ("FDCA"). Defendant argues that the FDCA does not provide a private right of action under which plaintiffs may bring suit.

The FDCA provides that all such proceedings for the enforcement or to restrain violations of the Act shall be by and in the name of the United States (with one exception not applicable here). 21 U.S.C. § 337(a). The Supreme Court has stated that the FDCA leaves no doubt that it is the federal government rather than private litigants who are authorized to file suit for noncompliance with the Act. *Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S.Ct. 1012, 1018 (2001).<sup>3</sup>

For these reasons, there is no private right of action for violation of the FDCA. Defendant's Motion for Summary Judgment on the negligence *per se* claim is granted, and that claim is dismissed.

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<sup>3</sup> In another case from Georgia, the court noted that no private right of action exists for a violation of the FDCA. *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284, n. 10 (11th Cir. 2002). Plaintiff may argue, as did the plaintiff in *Ellis*, that Defendant's warnings fall short of the standards set forth by Georgia law and/or the FDCA, but that does not create a separate private right of action for violation of the FDCA where the statute expressly prohibits such a claim.

## STRICT LIABILITY

To establish her strict liability claim<sup>4</sup> under Georgia law, Plaintiff must show that the product, when sold, was not merchantable and reasonably suited to the use intended and its condition when sold was the proximate cause of her injury. *Williams v. American Medical Systems*, 548 S.E.2d 371, 373-74 (Ga. Ct. App. 2001).

Defendant argues that Georgia courts apply a risk-utility analysis to strict liability claims involving defective drugs. Such an analysis involves the weighing of a number of factors, including the usefulness of the product, the gravity and severity of the danger caused by the design of the product, the avoidability of the danger, the efficacy of any warnings, the ability to eliminate the danger without impairing the product's usefulness, and the user's ability to avoid the danger. *Bryant v. Hoffmann-LaRoche, Inc.*, 585 S.E.2d 723, 730 (Ga. Ct. App. 2003). The weighing of these factors is generally a question for the jury. *Id.* Certainly the issue of the efficacy of the warnings is hotly contested in this action, precluding summary judgment.

Defendant also contends that it is entitled to the protections of comment k to the Restatement (Second) of Torts, § 402A, which protects manufacturers of prescription medications which are unavoidably safe. Under Georgia law, comment k provides protection against strict liability only where the product is properly prepared and accompanied by proper directions and warnings. *Bryant*, 585 S.E.2d at 727. Thus, it does not apply to claims of failure to warn. *Id.*

Therefore, Defendant's Motion for Summary Judgment with regard to Plaintiff's strict liability failure to warn claim is denied.

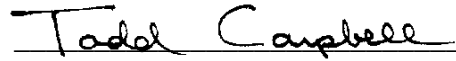
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<sup>4</sup> Plaintiff admits she has no manufacturing defect claim. Docket No. 3571.

CONCLUSION

For all these reasons, Defendant's Motion for Summary Judgment (Docket No. 3476) is GRANTED in part and DENIED in part. Plaintiff's claim for negligence *per se* is dismissed.

IT IS SO ORDERED.

  
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TODD J. CAMPBELL  
UNITED STATES DISTRICT JUDGE