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:	)
3:08-0908 (McDaniel)	)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 3504). For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part as follows. Plaintiff's claim for negligence *per se* is DISMISSED.

FACTS

Plaintiff brought this action against Novartis Pharmaceuticals Corporation, alleging that Novartis' drug Aredia caused his mother, Eula Mae McDaniel, to develop osteonecrosis of the jaw ("ONJ"). Plaintiff has alleged causes of action for strict liability and negligence, including failure to warn and negligence *per se*. Plaintiff also seeks punitive damages and damages for loss of consortium. 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)).

IDENTITY OF PRODUCT

Defendant first argues that Plaintiff cannot show that Mrs. McDaniel received more than three doses of Aredia because she has not identified the drug that she received from April 2001 through September 2003. If she received only three doses of Aredia, Defendant avers, then it is entitled to summary judgment because Aredia could not have caused her injuries. Docket No. 3506, p. 10.[1]

Defendant cites a May 15, 2008, letter from Robert Germany for its assertion that Plaintiff cannot identify the product which she received after April 2001. That letter (Docket No. 3506-3) includes Mr. Germany's subpoena to St. Edward's Hospital in Fort Smith, Arkansas, for documents "identifying the source of all pamidronate administered to Mrs. McDaniel" after April 2001. Thus,

[1] Defendant cites the testimony of Plaintiffs' expert Dr. Robert Marx, who has opined that three doses of Aredia would not be sufficient to put a person at an increased risk for developing ONJ. Docket No. 3506, p.10.

on May 15, 2008, Plaintiff's counsel was still attempting to identify the drug provided to Mrs. McDaniel after April 2001.

Plaintiff contends that the medical records of Mrs. McDaniels' oncologist, Dr. Anthony Courtney, reveal that Mrs. McDaniel in fact was prescribed Aredia during this time period. Plaintiff asserts that those medical records are Exhibit 5 to a "Notice of Filing," but cites no specific docket number for such a document. The Notice of Filing at Docket No. 3592 includes no attached exhibits.

As indicated in the Court's Order on Defendant's Motion to Exclude Causation Testimony of Plaintiff's Non-Retained Experts in this case, the Court is not required to search the record for evidence which is not properly identified by a party. Plaintiff has failed to direct the Court to the medical records of Dr. Courtney upon which he relies.

Neither has Plaintiff cited the Court to any response from St. Edward's Hospital or any other medical provider identifying the manufacturer of the drug which Mrs. McDaniel was given. As noted, Plaintiff cites to an "office note"of Dr. Courtney which, according to Plaintiff, reveals that Mrs. McDaniel was prescribed Aredia from January 5, 2001, through September 8, 2003.

Defendant represents that Dr. Courtney has not been located and has not been deposed, Docket No. 3506; but Defendant has not challenged the authenticity of Dr. Courtney's medical records, wherever they may be in the record. Defense counsel argued at the hearing that the mere mention of Aredia in medical records does not mean that Aredia, rather than a generic drug, was actually given. Thus, if Dr. Courtney's records do reflect that Aredia was given, there is a genuine issue of material fact as to whether that assertion is true.

A fundamental principle of traditional products liability law is that the plaintiff must prove that the defendant supplied the product which caused the injury.[2] Nonetheless, the parties agree that Mrs. McDaniel received at least three doses of Aredia. The Court believes that Plaintiff has demonstrated a genuine issue of material fact as to how many doses of Aredia Mrs. McDaniel received and what, if any, effect those doses had upon her ONJ. Accordingly, Defendant's Motion is denied on this issue.

CAUSATION

Defendant argues that Plaintiff cannot provide sufficient admissible expert testimony concerning specific causation in this case. Plaintiffs in Arkansas must introduce sufficient evidence to allow a jury to find that more likely than not their exposure to a particular defendant's product was a substantial factor in producing their injuries. *Jackson v. Anchor Packing Co.*, 994 F.2d 1295, 1303 (8th Cir. 1993) (*cited in Fullington v. Pfizer, Inc.*, 2010 WL 3632747 at * 1 (E.D. Ark. Sept. 17, 2010)).

This Court has previously found that there are genuine issues of material fact as to whether Aredia and Zometa generally can cause ONJ, and that ruling applies here. Defendant asserts that Plaintiff cannot prove that Aredia caused Mrs. McDaniel's specific ONJ because Plaintiff has no reliable expert testimony on this issue. The Court has denied Defendant's Motion to Exclude the expert causation testimony of Dr. Robert Kraut, who opined that Mrs. McDaniel's ONJ was bisphosphonate-induced, secondary to her use of Aredia. Dr. Kraut's opinion is sufficient to create

[2] This Court has previously dismissed cases in this litigation where the Plaintiff could not identify the manufacturer of the drug, stating that the information concerning which drug was given to a Plaintiff herein is information within the reach of the Plaintiff, information held by the Plaintiff's health care providers and available to the Plaintiff. *See, e.g.*, Docket No. 3259.

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

Defendant argues first that Plaintiff cannot establish that Novartis' warnings were inadequate. Arkansas recognizes the existence of the Learned Intermediary Doctrine in failure to warn cases. *In re Prempro Products Liability Litigation*, 514 F.3d 825, 830 (8th Cir. 2008). Under this doctrine, adequate warning to prescribing physicians obviates the need for manufacturers of prescription drugs to warn ultimate consumers directly. *Id*. The Court has already held that there are genuine issues of material fact as to the adequacy of Defendant's Aredia and Zometa warnings, and that ruling applies here.

Defendant contends, however, that Plaintiff has no evidence that a different warning would have prevented Mrs. McDaniel's injuries. Once a plaintiff proves the lack of an adequate warning, a presumption arises that the user would have read and heeded adequate warnings. *Bushong v. Garman Co.*, 843 S.W.2d 807, 811 (Ark. 1992). This presumption may be rebutted by evidence that an adequate warning would have been futile under the circumstances. *Id*. The presumption that an adequate warning would have been read and heeded does not eliminate the plaintiff's ultimate burden of proving that the inadequate warnings were the proximate cause of the plaintiff's injuries. *Boerner v. Brown & Williamson Tobacco Corp.*, 260 F.3d 837, 844 (8th Cir. 2001).

Defendant maintains that Dr. Courtney, Mrs. McDaniel's oncologist, tried to re-start her Aredia after she was diagnosed with ONJ. Docket No. 3506, p. 16. Dr. Courtney's record (attached to Defendant's Statement of Material Facts as Ex. 18) indicates that the oncologist wrote, at some point, "consider restarting Aredia?" The medical record attached as Ex. 11 to Defendant's

Statement of Material Facts indicates that Mrs. McDaniel's Aredia was discontinued on "8 Sep. 2003." The Court finds that Dr. Courtney's question in the medical records is insufficient evidence that Dr. Courtney would have, in fact, recommended restarting Mrs. McDaniel's Aredia or that different warnings would have been futile.

In addition, there are genuine issues of material fact as to whether, given different warnings, Mrs. McDaniel would have agreed to any suggestion that she continue or restart Aredia.[3] Her Aredia was, in fact, discontinued. There are genuine issues of material fact as to whether different warnings would have changed the behavior of Mrs. McDaniel or her health care providers. Thus, Defendant has not proven that an adequate warning would have been futile under these circumstances.

Defendant's arguments concerning whether a different warning would have mattered show why *Plaintiff* is not entitled to summary judgment on this issue. Nonetheless, there are genuine issues of material fact which preclude summary judgment for Defendant as well. Accordingly, Defendant's Motion for Summary Judgment on Plaintiff's failure to warn claim is denied.

STRICT LIABILITY

Under Arkansas law, a supplier of a product is strictly liable for an injury caused by the product if (1) the product was in a defective condition that rendered it unreasonably dangerous and (2) the defective condition was a proximate cause of the injury. *Boerner*, 260 F.3d at 842. The

[3] Plaintiff claims that Mrs. McDaniel refused to restart the drug, even when her oncologist advised it, again relying upon records of Dr. Courtney for which no specific citation to the docket is given. Docket No. 3582, pp. 15-16. As indicated above, the Court is not required to search the record for materials incorrectly cited or named on the docket.

plaintiff may prove the defective condition by showing defective design, defective manufacture, or inadequate warning. *Id*. Plaintiff here alleges inadequate warning.

"Unreasonably dangerous" means that a product is dangerous to an extent beyond that which would have been contemplated by the ordinary and reasonable buyer, consumer or user, who acquires or uses the product. Ark. Stat. Ann. § 16-116-102(7). What would have been contemplated by the "ordinary and reasonable" consumer is clearly a jury question. Moreover, whether the alleged inadequate warnings made Defendant's product unreasonably dangerous is also a genuine issue of material fact precluding summary judgment.

Defendant argues 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 Arkansas law, comment k does not offer protection from allegations of inadequate warnings. *West v. Searle & Co., G.D.*, 806 S.W.2d 608, 613 (Ark. 1991). As Defendant points out, comment k protects manufacturers of prescription medicines "where an appropriate warning is provided." Obviously, whether such an appropriate warning was provided for these drugs is hotly contested in this litigation.

For these reasons, Defendant's Motion for Summary Judgment on the strict liability claim is DENIED.

NEGLIGENCE *PER SE*

Plaintiff has claimed 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 statute itself provides that all such proceedings for the enforcement or to restrain violations of the FDCA 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).

Given this clear statutory guidance and Supreme Court language specific to the FDCA, Plaintiff's citation to cases about state alcohol laws is not persuasive. For these reasons, Defendant's Motion for Summary Judgment on this issue is granted, and Plaintiff's claim for negligence *per se* is dismissed.

LOSS OF CONSORTIUM

In light of the above rulings, Defendant's Motion for Summary Judgment on Plaintiff's loss of consortium claim is denied.

CONCLUSION

For the above reasons, Defendant's Motion for Summary Judgment (Docket No. 3504) is GRANTED in part and DENIED in part. Plaintiff's claim for negligence *per se* is DISMISSED.

IT IS SO ORDERED.

Todd Campbell

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE