

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:	)
3:08-0924 (Victor Brown)	)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 3434). For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part as follows.

FACTS

Plaintiff Victor Brown has asserted claims against Defendant for strict liability and negligence (including negligence *per se*), alleging that Defendant's drugs, Aredia and Zometa, caused Plaintiff to develop osteonecrosis of the jaw ("ONJ"). Mr. Brown's wife has asserted a claim for loss of consortium. Defendant has moved for summary judgment on all of Plaintiffs' 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)).

#### STRICT LIABILITY

Plaintiffs have conceded that their claims for strict liability, design defect and manufacturing defect fail as a matter of North Carolina law. Docket No. 3568, p. 20. Accordingly, Defendant's Motion for Summary Judgment is GRANTED on Plaintiffs' strict liability, design defect and manufacturing defect claims, and those claims are DISMISSED.

#### CAUSATION

Defendant argues that Plaintiffs cannot establish that Aredia and/or Zometa caused Mr. Brown's ONJ. The Court has previously found that there are genuine issues of material fact as to whether Aredia and Zometa generally can cause ONJ. Defendant contends that Plaintiffs have no admissible expert testimony<sup>1</sup> to show that these drugs caused Mr. Brown's ONJ specifically.

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<sup>1</sup> Where an injury is complicated, such as in this case, expert medical testimony on the issue of causation must be provided. *Driggers v. Sofamore*, 44 F.Supp.2d 760, 764-65 (M.D. N.C. 1998).

Under North Carolina law, which the parties agree applies in this case, a manufacturer may not be held liable for a claim based on inadequate warnings unless the failure to provide adequate warnings was a proximate cause of the Plaintiffs' injuries. *DeWitt v. Eveready Battery Co.*, 550 S.E.2d 511, 517-18 (N.C. Ct. App. 2001); *see also* N.C. Stat. § 99B-5(a). In addition, to hold a defendant responsible for a plaintiff's injuries in a negligence<sup>2</sup> action, defendant's negligence must have been a substantial factor of the particular injuries for which the plaintiff seeks recovery. *Gaines v. Cumberland County Hospital System, Inc.*, 672 S.E.2d 713, 716 (N.C. Ct. App. 2009).

Here, Plaintiffs have offered expert testimony from Dr. Yoh Sawatari, who opines that Mr. Brown suffered from bisphosphonate-induced osteonecrosis of the jaw, related to the significant administration of IV bisphosphonates (Aredia and Zometa). Docket No. 3488-3. The Court has, contemporaneously herewith, denied Defendant's Motion to Exclude the testimony of Dr. Sawatari. Therefore, Plaintiffs have presented sufficient evidence to establish a factual dispute on this issue, and Defendant's Motion for Summary Judgment on the issue of specific causation is denied.

#### FAILURE TO WARN

This Court has previously found that there are genuine issues of material fact as to whether Novartis' warnings concerning Aredia and Zometa were inadequate. Defendant argues, however, that Plaintiffs cannot show that any alleged inadequacy of warnings was a proximate cause of Mr. Brown's ONJ.

Defendant points out that Mr. Brown's oncologist, Dr. Arb, has testified that, knowing what she knows now, she still would have prescribed Aredia and Zometa for Mr. Brown. She also

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<sup>2</sup> Because North Carolina does not recognize strict liability in products liability actions, Plaintiffs' claims are based upon negligence. *See Driggers*, 44 F.Supp.2d at 766.

testified, however, that she now advises all patients for whom she is prescribing bisphosphonates that there have been problems with the jaw associated with bisphosphonate treatment. Docket No. 3568-3, p. 17 (Arb Deposition, p. 57). She stated that she tells her patients to advise her any time they undergo oral surgery and to advise the oral surgeon that they are on bisphosphonates. *Id.*, pp. 17-18 (deposition, pp.57-58). She further stated that she would have given that same warning to Mr. Brown about the risk of ONJ if she had known. *Id.*, p. 19 (deposition, p. 63).

Plaintiffs have also presented the Affidavit of Mr. Brown, who states that if he had been warned of the risk of ONJ associated with the use of Aredia and Zometa, he would not have taken the drugs and would have insisted on greater vigilance and dental monitoring to protect his jaw. Docket No. 3568-4.

The Court finds that Plaintiffs have presented sufficient evidence to show a genuine issue of material fact as to whether adequate warnings would have made a difference in the behavior of Mr. Brown and his health care providers. Accordingly, Defendant's Motion for Summary Judgment on the failure to warn issue is denied.

#### NEGLIGENCE *PER SE*

Plaintiffs have admitted that the negligence *per se* doctrine does not create new causes of action. Docket No. 3568, p. 19. In addition, the Federal Food, Drug and Cosmetic Act ("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 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).

Therefore, to the extent Plaintiffs' negligence *per se* claim purports to be a separate cause of action, Defendant's Motion for Summary Judgment is granted. To the extent Plaintiffs wish to argue that the negligence *per se* doctrine creates some sort of standard by which to judge Defendant's behavior, the Court need not reach that issue and Defendant's Motion is moot.

#### LOSS OF CONSORTIUM

To the extent Plaintiffs' claims for negligent failure to warn remain, Mrs. Brown's loss of consortium claim remains as well.

#### CONCLUSION

For these reasons, Defendant's Motion for Summary Judgment (Docket No.3434) is GRANTED in part and DENIED in part. Plaintiffs' claims for strict liability, design defect, manufacturing defect and negligence *per se* are DISMISSED.

IT IS SO ORDERED.

  
TODD J. CAMPBELL  
UNITED STATES DISTRICT JUDGE