

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)
No. 3:06-0659 (Emerson/Crews))

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 2269). For the reasons stated herein, Defendant's Motion is GRANTED, and Plaintiff's claims are DISMISSED.

FACTS

Plaintiff Emerson brings this action against Novartis alleging that Novartis' drugs, Aredia and Zometa, caused her deceased father to develop osteonecrosis of the jaw ("ONJ"). Plaintiff alleges causes of action for (1) negligence - testing and failure to warn, (2) strict liability - defective design, (3) strict liability - defective manufacture, and (4) strict liability - failure to warn. Defendant has moved for summary judgment on all claims.

SUMMARY JUDGMENT

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). 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. *Van Gorder v. Grand Trunk Western Railroad, Inc.*, 509 F.3d 265, 268 (6th Cir. 2007). In order to defeat a summary judgment motion, the nonmoving

party must provide more than a scintilla of evidence; that is, the nonmoving party must present evidence sufficient to permit a reasonable jury to find in its favor. *Van Gorder*, 509 F.3d at 268. Entry of summary judgment is appropriate against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's cases, and on which that party will bear the burden of proof at trial. *Id.*

FLORIDA STATUTORY PRESUMPTION

Florida law provides that in a products liability action brought against a manufacturer, there is a rebuttable presumption that the product is not defective or unreasonably dangerous and the manufacturer is not liable if, at the time the product was sold, (1) it complied with federal codes, statutes, rules, regulations or standards relevant to the event causing the harm; (2) the codes, statutes, rules, regulations or standards were designed to prevent the type of harm that allegedly occurred; and (3) compliance with the codes, statutes, rules, regulations or standards was required as a condition for selling or distributing the product. Fla. St. Ann. § 768.1256(1).

Defendant asserts that it is entitled to the presumption set forth in this statute and that Plaintiff cannot rebut the presumption. Plaintiff does not dispute that the three elements of the statute are met and, thus, does not dispute that Defendant is entitled to the presumption of no liability.

Plaintiff argues instead, with no citation to the record, that she can rebut the presumption because the FDA approvals of Aredia and Zometa were obtained improperly. Docket No. 2620, p. 21. Plaintiff asserts, again with no citation to the record, that Defendant's product does not meet FDA standards. *Id.* The only way Plaintiff attempts to rebut this statutory presumption is by alleging that the FDA approvals were improperly obtained, and the only evidence Plaintiff offers to argue that

the FDA approvals were improperly obtained is her counsel's conclusory statements, with no citations to any admissible evidence in this record. Docket No. 2620, p. 21.


Even if Plaintiff did have admissible evidence to show that the FDA approvals for Aredia and Zometa were improperly obtained, improperly obtained FDA approvals are an issue that is pre-empted as a "fraud-on-the-agency" claim, pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 121 S.Ct. 1012, 1017 (2001). In *Buckman*, the Court found that the plaintiffs' state law fraud-on-the-FDA claims conflicted with and were therefore impliedly preempted by the Federal Food, Drug and Cosmetic Act ("FDCA"). Noting that policing fraud against federal agencies is hardly "a field which the States have traditionally occupied," the Court held that it is the FDA's exclusive responsibility to police fraud or wrongdoing in connection with approval of products before the FDA. *Id.*

Thus, the only argument put forth by the Plaintiff to rebut the statutory presumption of no liability of Novartis in this products liability action is pre-empted by the FDCA.¹ Accordingly, Defendant is entitled to the protection of Fla. St. Ann. § 768.1256(1) as to all of Plaintiff's claims.

CONCLUSION

Having found that Novartis is entitled to the protection of the Florida statute, the Court need not address Defendant's other arguments. Defendant's Motion for Summary Judgment (Docket No. 2269) is GRANTED, and Plaintiff's claims are DISMISSED.

IT IS SO ORDERED.



TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE

¹ Nothing in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), which is distinguishable from this action, changes this result.