Bartoli v. Novartis Pharmaceuticals Corporation Doc. 150

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

IN RE:	)
AREDIA and ZOMETA PRODUCTS	)
LIABILITY LITIGATION	)
	)
This Document Relates to:	)
Case No. 3:06-0377 (Thomas)	)
Case No. 3:06-0381 (Hogan)	) NO. 3:06-MD-1760
Case No. 3:06-0521 (Brodie)	) JUDGE CAMPBELL
Case No. 3:06-0550 (White)	)
Case No. 3:06-0659 (Crews)	)
Case No. 3:08-0068 (Fussman)	)
Case No. 3:08-0069 (Forman)	)
Case No. 3:08-0071 (Deutsch)	)
Case No. 3:08-1157 (Anderson)	)
Case No. 3:08-1156 (Melau)	)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment on the Adequacy of Aredia and Zometa Warnings (Docket No. 2283). The Court held a hearing on July 27, 2009. For the reasons stated herein, Defendant's Motion is DENIED.

Defendant asserts that it is entitled to summary judgment on Plaintiffs' failure to warn claims because the labeling for Aredia and Zometa adequately conveyed the information known or knowable to Defendant at the time each label was approved, and the labels are adequate as a matter of law. Specifically, Defendant maintains that, prior to 2003, it had no duty to warn because no cases of ONJ had been reported to Defendant. Once such cases were reported, Defendant argues, it conducted a comprehensive investigation and its labeling changes in 2003 and 2004 and "Dear Doctor" letter in 2004 were adequate.

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Defendant also contends that Plaintiffs have no admissible testimony to contest the adequacy of its labels, even though such expert testimony is required. Whether the warnings were adequate to warn a physician of the possibility that the drug might be causing the condition experienced must be presented through the testimony of an expert. *Colville v. Pharmacia & Upjohn Co., LLC*, 565 F.Supp.2d 1314, 1321 (N.D. Fla. 2008); *Haggerty v. Upjohn Co.*, 950 F.Supp. 1160, 1168 (S.D. Fla. 1996).

Defendant asserts that Plaintiffs' warning experts should be excluded because none of them proposed alternative labeling language. Some courts have excluded expert testimony because the expert did not propose alternative warning language. For example, in *Brown v. The Raymond Co.*, 432 F.3d 640, 648 (6th Cir. 2005), the court held that the expert's failure to propose alternative warnings subject to empirical testing rendered his testimony unreliable and irrelevant to the trier of fact. In *Bourelle v. Crown Equipment Corp.*, 220 F.3d 532, 538 (7th Cir. 2000), the court held that the same reliability requirements that apply to alternative design apply to alternative warnings. The expert's testimony in *Bourelle* was excluded because he failed to draft or test an alternative warning. *Id*. at 539; *see also Dhillon v. Crown Controls Corp.*, 269 F.3d 865, 870 (7th Cir. 2001) and *Miller v. Pfizer, Inc.*, 196 F.Supp.2d 1062, 1089-90 (D. Kan. 2002).

Defendant also contends that, pursuant to the "learned intermediary doctrine," its warnings were sufficient to adequately warn and instruct physicians responsible for prescribing the medication. Under the learned intermediary doctrine, manufacturers of prescription drugs escape liability for failure to instruct and warn consumers so long as they adequately instruct and warn physicians responsible for prescribing the medication. *In re Meridia Products Liability Litigation*, 328 F.Supp.2d 791, 811 (N.D. Ohio 2004).

Plaintiffs argue that Defendant *should* have known about the risks of ONJ related to bisophosphonates even before Aredia was approved by the FDA and certainly by 2003. Plaintiffs assert that whether Defendant's labeling adequately conveyed information known or knowable to Defendant at the time involves multiple issues of fact. Plaintiffs also contend that summary judgment cannot be granted because the various state laws involved in these cases differ as to their standards for failure to warn and Defendant has simply made a "blanket" argument. Plaintiffs assert that their experts have clearly identified the problems with Defendant's drug labels as seeking to blame "alternative, well-documented risk factors" that are not in fact risk factors for ONJ. Plaintiffs' proposed alternative labeling language was, at a minimum, language omitting the words "well-documented" and/or eliminating the reference to alternative risk factors altogether.

As evidenced by the opposing briefs and the opposing arguments at the hearing, Defendant vigorously asserts that there are no material disputed facts and its warnings were adequate as a matter of law. Plaintiffs argue with equally zealous energy that Defendant's labels included blatant falsehoods and overtly misleading information. There are a myriad of factual issues here. For example, there are factual questions concerning what Defendant knew or should have known when; whether there are, in fact other "risk factors" for ONJ and what those are; and whether Defendant had adequately conveyed information to physicians of the known or knowable risk at the time of each Plaintiff's treatment. Defendant's experts say the warnings were adequate, and Plaintiffs' experts say the warnings were false and misleading. The Court finds that the jury will have to determine which experts are credible, in whole or in part, and which side of this argument to believe.

Defendant has not carried its burden to show that there are no genuine issues of material facts or that it is entitled to judgment as a matter of law on Plaintiffs' failure to warn claims. Therefore,

Defendant's Motion for Summary Judgment on the Adequacy of Aredia and Zometa Warnings (Docket No. 2283) is DENIED.

IT IS SO ORDERED.

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE