UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	Master File No. 06 MD 1789 (JFK)
This document relates to: Scheinberg v. Merck & Co., Inc., No. 08 Civ. 4119 (JFK)	MEMORANDUM OPINION & ORDER

JOHN F. KEENAN, United States District Judge:

Before the Court is Defendant's motion for judgment as a matter of law under Rule 50(b) on Plaintiff's failure to warn claim. For the reasons that follow, the motion is denied.

I. Background

This was the fifth case selected for trial as a bellwether in the In re Fosamax Products Liability Litigation multidistrict litigation ("MDL"). This MDL involves claims that Fosamax, a drug designed and produced by defendant Merck Sharp & Dohme Corp. ("Merck"), caused users of Fosamax to suffer from a condition known as osteonecrosis of the jaw ("ONJ"). In the instant case, plaintiff Rhoda Scheinberg ("Scheinberg" or "Plaintiff") brought strict liability and negligence claims on theories of design defect and failure to warn, in addition to claims for fraudulent misrepresentation and concealment, and breach of express and implied warranty. She also sought punitive damages. Scheinberg began taking Fosamax in 2000, and continued taking it through 2006. Her prescribing physician

between 2004 and 2006 was Dr. Dunn. (Def. 56.1 ¶ 1.) On October 30, 2006, Plaintiff had a tooth extraction and subsequently suffered from delayed healing. (Id. ¶¶ 3-4.) Plaintiff's expert, Dr. Richard Kraut, opined that the delay Scheinberg experienced in healing from the tooth extraction was ONJ, and that her use of Fosamax caused it. Another expert proffered by Plaintiff, Dr. Suzanne Parisian, testified that the Fosamax label was insufficient to warn of the risk of ONJ.

Prior to trial, Defendant moved for summary judgment on all claims. The Court granted the Defendant's motion with respect to Plaintiff's claims for breach of warranty, fraudulent misrepresentation and concealment, and punitive damages, but denied it with respect to Plaintiff's claims for design defect and failure to warn.

Merck twice moved for judgment as a matter of law during trial pursuant to Rule 50(a): at the close of Plaintiff's case, and again after both sides rested. The Court denied both motions and the case was submitted to the jury. On February 5, 2013, the jury returned a verdict in favor of Merck on the design defect claim and in favor of Scheinberg on the failure to warn claim, awarding Scheinberg $285,000.

II. Discussion

Merck timely filed the instant motion pursuant to Rule 50(b) on March 5, 2013. It contends that it is entitled to

judgment as a matter of law on Plaintiff's failure to warn claim.

A. Rule 50

"Under Rule 50(a), a party may move for judgment as a matter of law during trial at any time prior to the submission of the case to the jury." Galdieri-Ambrosini v. Nat'l Realty & Dev. Corp., 136 F.3d 276, 286 (2d Cir. 1998); see Fed. R. Civ. P. 50(a). Under Rule 50(b), if the Court does not grant the Rule 50(a) motion at the close of evidence, the moving party may renew its motion for judgment as a matter of law under Rule 50(b) within 25 days of an unfavorable judgment, but it "is limited to those grounds that were specifically raised in the prior [Rule 50(a) motion]." Galdieri-Ambrosini, 136 F.3d at 286; see Fed. R. Civ. P. 50(b).

The movant faces a "high bar," Lavin-McEleney v. Marist Coll., 239 F.3d 476, 479 (2d Cir. 2001); motions for judgment as a matter of law "should be granted cautiously and sparingly." Meloff v. N.Y. Life Ins. Co., 240 F.3d 138, 145 (2d Cir. 2001). In deciding the motion, the Court "must view the evidence in a light most favorable to the non-movant and grant that party every reasonable inference that the jury might have drawn in its favor." Merrill Lynch Interfunding, Inc. v. Argenti, 155 F.3d 113, 120-21 (2d Cir. 1998) (quoting Samuels v. Air Transport Local 504, 992 F.2d 12, 14 (2d Cir. 1993)). The Court "may not

itself weigh the credibility of witnesses or consider the weight of the evidence." Galdieri-Ambrosini, 136 F.3d at 286. The Court may properly grant such a motion only where it "finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for" the non-movant. Fed. R. Civ. P. 50(a); see Arlio v. Lively, 474 F.3d 46, 51 (2d Cir. 2007) (holding that judgment as a matter of law should be granted when "the evidence, viewed in the light most favorable to the nonmoving party is insufficient to permit a reasonable juror to find in [the non-moving party's] favor").

B. Analysis

Merck argues that it is entitled to judgment as a matter of law because the Fosamax label was sufficient under New York law. According to Merck, the label warned doctors of the "precise malady" incurred by Plaintiff, which is the New York standard. Therefore, Merck avers, no reasonable juror could have concluded that the label was inadequate. Merck points to nine cases where labels that include the "precise malady" alleged by Plaintiff were determined adequate as a matter of law.

Merck is correct that courts applying New York law have held that "prescription medicine warnings are adequate when . . . information regarding the precise malady incurred was communicated in the prescribing information." Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 284-85 (S.D.N.Y. 2009); see

also Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 260 (E.D.N.Y. 1999) (granting summary judgment to drug manufacturer where manufacturer had warned physician "against the precise usage and injuries in question"). But a warning is not automatically sufficient simply because it includes certain "magic words." While "the language of these decisions might at first seem to indicate that a manufacturer satisfies its duty to warn of a drug's side effects simply by mentioning those side effects in the drug's label," courts have recognized the importance of considering "not merely the existence of a pertinent warning, but also the qualitative adequacy of the warning. DiBartolo v. Abbott Laboratories, No. 12 Civ. 900, 2012 WL 6681704 at *7 (S.D.N.Y. Dec. 21, 2012).

Indeed, in determining whether a warning is adequate as a matter of law, the court should "evaluate the [warning]'s language for its accuracy, clarity and relative consistency." Martin v. Hacker, 83 N.Y.2d 1, 11 (1993). A warning is accurate if it is "correct, fully descriptive and complete, and . . . convey[s] updated information as to all of the drug's known side effects." Id. (citation omitted). It is clear if it employs language that is "direct, unequivocal and sufficiently forceful to convey the risk." Id. An otherwise clear warning "may be obscured by inconsistencies or contradictory statements made in different sections of the package insert regarding the same side

effect or from language in a later section that dilutes the intensity of a caveat made in an earlier section." Id. A warning with such contradictions may nonetheless be adequate "if the language of a particular admonition against a side effect is precise, direct, and unequivocal and has sufficient force." Id. at 12. Courts must evaluate the entire warning, as any vagueness that appears from reading individual sentences in isolation "may be overcome if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." Id.

Merck has emphasized the phrase "precise malady," while disregarding the other elements set forth in New York. The Court does not accept that simply because the Fosamax label mentions the malady "osteonecrosis of the jaw," it is sufficient as a matter of law. Rather, whether the name of the malady incurred by Plaintiff was included is but one consideration in evaluating the Fosamax label "as a whole."

Merck attempts to support its position by citing to a multitude of cases that apply New York law, despite conceding that failure to warn is a fact-specific inquiry. It relies heavily on Martin v. Hacker, 83 N.Y.2d 1 (1993), a case in which the Court of Appeals affirmed the lower court's grant of summary judgment on Plaintiff's failure to warn claim. However, as another court more recently noted, "in the Martin case the Court

of Appeals considered a situation where the plaintiff presented no expert evidence as to the adequacy of the manufacturer's warning and therefore the court held the warning adequate based on its analysis." Smith v. Johnson & Johnson Co., 800 N.Y.S.2d 357 (Table) (Sup. Ct. 2004). The court in Smith found that "Plaintiff's submission of an expert opinion as to the inadequacy of defendants' warnings is sufficient to raise an issue of fact precluding summary judgment where the alleged deficiency in the warnings is related to the condition which is alleged to have caused the decedent's death." Id. This case is distinguishable from Martin for the same reason set forth in Smith: Plaintiff called an expert witness.

New York courts have routinely advised that the sufficiency of a label is a factual determination to be made by a jury. "Under New York law, the jury does not need expert testimony to find a label inadequate, but may use its own judgment considering all the circumstances." Billiar v. Minnesota Min. and Mfg. Co., 623 F.2d 240, 247 (2d Cir. 1980).

The jury was presented with testimony regarding all aspects of the Fosamax label. Dr. Dunn and Dr. Parisian testified on the issue of Fosamax's efficacy for patients with low body mass but without vertebral fractures. Dr. Parisian testified that the label failed to include information about the "limited efficacy" of Fosamax. (Tr. at 1094:4-1096:14). Dr. Dunn

testified that if she had been aware that the risk of ONJ in Fosamax users increases as the duration of use increases, she would not use Fosamax. (Tr. at 892:25-893:14.) Dr. Dunn later reiterated that if she had known that Fosamax was less effective for patients with a T-score of better than -2.5, she would have taken Scheinberg off Fosamax. (Tr. at 902:19-903:11.)

The jury also heard testimony from Dr. Parisian and Dr. Dunn that the label was inadequate. As discussed above, a factor to be considered in a failure to warn claim is whether the label is "sufficiently forceful to convey the risk." Martin, 83 N.Y.2d at 11 During her testimony, Dr. Parisian questioned whether the label properly conveyed the causal relationship between Fosamax and ONJ, noting that the label did not make clear that there had been reports of ONJ by patients taking Fosamax. Dr. Parisian said the following about the 2005 label:

> Well, it doesn't convey that it's been associated with Fosamax and ONJ. It doesn't convey that it's been associated with an oral bisphosphonate like Fosamsax. It doesn't talk about the seriousness or didn't talk about the adverse event reports that the company's receiving. So it doesn't convey the information that the company has in terms of their documents about the risk of ONJ.

(Tr. at 1077:17-19-1079:9.) Similarly, Dr. Dunn testified that the label did not inform her of the severity or seriousness of ONJ. (Tr. at 892:22-24.) Both doctors testified at length about the fact that the label did not convey the seriousness and

frequency of ONJ among Fosamax users. This testimony was properly submitted to the jury as evidence of failure to warn.

Finally, the jury was presented with testimony from Dr. Parisian about other drugs' labels that addressed ONJ and oral bisphosphonates. Under New York law, evidence that a manufacturer "diluted" a label or introduced confusion or inconsistencies is relevant to the failure to warn inquiry. The Plaintiff introduced evidence to show that the FDA had suggested a label change to include language that most cases of ONJ "have been in patients treated with bisphosphonates intravenously, but some have been in patients treated orally." The jury learned that Merck rejected this proposed change. Dr. Parisian also spoke to the jury about the labels that were used by Fosamax competitors, namely Actonel and Boniva. These drug labels reflected the FDA's proposed language almost verbatim. In considering the competitors' labels and the suggestions made by the FDA, a reasonable juror could have concluded that Merck's ONJ precaution was inadequate. Indeed, as the Court noted in its Daubert opinion, "jurors will be able to read the labels and conduct this comparison on their own."

It is worth noting that the jury, which Merck now contends was "unreasonable," returned a verdict in Merck's favor on the design defect claim. Additionally, in finding Merck liable on a failure to warn theory, it awarded Plaintiff only a modest

amount in damages. It would be a gross abuse of discretion for the Court to find only a portion of the jury's verdict unreasonable, eschewing evidence that the jury prudently weighed the case presented to them.

III. Conclusion

For the reasons stated above, Defendant's motion for judgment as a matter of law is denied.

SO ORDERED.

Dated: New York, New York
July 1, 2013

JOHN F. KEENAN
United States District Judge