UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	1:06-MD-1789-JFK
This document relates to: Judith Graves v. Merck & Co., Inc., No. 1:06-cv-5513-JFK	**MEMORANDUM OPINION & ORDER**

JOHN F. KEENAN, United States District Judge:

At oral argument on October 20, 2010, the Court addressed nine motions in limine made by the Plaintiff, Mrs. Judith Graves ("Graves"), and twenty-nine motions in limine made by the Defendant, Merck & Co., Inc. ("Merck"). After arguments were heard, the Court issued oral rulings on thirty-two of the motions, but reserved decision on six of the motions. The Court will address each of these motions below, in turn.

Graves' Motion in Limine #8

Graves moves to exclude "fear mongering" and argument that a verdict for the plaintiff would take a prescription choice away from doctors.

At oral argument, the Court reserved decision in part on this motion because the Court wished to make rulings based on the specific questions that would be posed to Dr. Bilezikian. Thus, the Court ordered Merck to provide the proposed questions. The Court continues to RESERVE judgment on this motion until it has received and reviewed Merck's submission.

Merck's Motion in Limine #2

Merck moves to exclude testimony from Dr. Robert Marx, D.D.S., concerning his opinion that Fosamax caused Graves' injury.

The Court reserved judgment on this motion because it was duplicative of Merck's motion to exclude expert testimony pursuant to Daubert v. Merrell Dow Pharms., 509 U.S. 579 (1993). In its recent Opinion and Order on the Daubert motion in this case, the Court granted Merck's motion to exclude Dr. Marx's testimony. Graves v. Merck, No. 1:06-cv-05513-JFK, slip op. at 9-10 (S.D.N.Y. Oct. 22, 2010). Therefore, the motion is GRANTED.

Merck's Motion in Limine #4

Merck moves to exclude evidence concerning risks of Fosamax use other than osteonecrosis of the jaw ("ONJ"), including myocardial infarction, atrial fibrillation, esophageal cancer, and lung cancer. Merck argues that such evidence is irrelevant and, alternatively, that such evidence lacks an adequate foundation.

With respect to the relevance of risks other than ONJ, the Court previously noted in Boles v. Merck & Co., Inc. that such evidence may be relevant to Merck's defense that Fosamax is not defectively designed because its benefits outweigh its risks. (Boles I Motions in Limine Hr'g Tr. at 480:4-14 (citing Adams v.

G.D. Searle & Co., 576 So. 2d 728, 733 (Fla. Dist. Ct. App. 1991)).)

However, before the Court can entertain evidence of other risks Fosamax may pose to a patient's health, Graves must establish by a preponderance of the evidence a proper foundation for her claim. Bourjaily v. United States, 483 U.S. 171, 176 (1987). That is to say, she must present sufficient evidence to show that Fosamax in fact causes these adverse events. To establish a proper foundation for her allegations that Fosamax causes risks such as myocardial infarction and femur fracture, Graves proffers the deposition testimony of Dr. Jane Cauley, an investigator for Merck's Fracture Intervention Trial ("FIT"), and a 2008 case-control chart review conducted by researchers from Cornell University's Hospital for Special Surgery. Graves proffers no evidence to show that Fosamax causes cancer. While Graves attempts to use Dr. Cauley's deposition to show that the FIT researchers found a relationship between Fosamax usage and myocardial infarction, Graves ignores Dr. Cauley's testimony that a safety report was never issued because "once the expert cardiologist reviewed and adjudicated all the records and the events, there it was--there was no association." (Cauley Dep. Tr. at 24:20-25:2.) Similarly, the article proffered by Graves to show that Fosamax causes femur fracture is inconclusive; the authors of that article state only that the fracture studies

"may be a consequence of [Fosamax] use . . . although further investigation is necessary." (Pl. Opp. Ex. 16 at 349.) The Court finds that Graves' proffer fails to establish a foundation for an association--much less a causal relationship--between Fosamax use and these alleged non-ONJ risks by a preponderance of the evidence.

As Graves has failed to establish an adequate foundation for the alleged non-ONJ risks of Fosamax, Merck's Motion in Limine #4 is GRANTED.

Merck's Motion in Limine #7

Merck moves to exclude testimony by Dr. Suzanne Parisian that Merck violated 21 C.F.R. §§ 314.70 and 314.80(b). The Court reserved decision on this motion at oral argument because it had not had an opportunity to assess the impact of a recent opinion cited in the parties' papers, Ingram v. Wyeth, Inc., No. 4:05-cv-00718-WRW, slip op. at 4 (E.D. Ark. Sept. 16, 2010) (excluding testimony of Dr. Parisian from the In re Prempro Products Liability Litigation as unreliable ipse dixit testimony). The Court has now reviewed that decision, and finds it unhelpful to the resolution of this motion.

Merck argues that Dr. Parisian's testimony is based merely on her ipse dixit, rather than a reliable method required by Fed. R. Evid. 702. This argument is duplicative of the argument presented in Merck's omnibus Daubert motion. See In re Fosamax

Prods. Liab. Litig., 645 F. Supp. 2d 164 (S.D.N.Y. 2009) ("July 2009 Daubert Opinion"). In ruling on the parties' omnibus Daubert motions, the Court found that Dr. Parisian's conclusions about Merck's compliance with federal regulations were based on an "appropriate methodology" and that "Dr. Parisian's assessment of the reasonableness of Merck's conduct in light of her experience and understanding of FDA regulations will be helpful to the jury." Id. at 190-91.

Merck argues that 21 C.F.R. § 314.70, also known as the "changes being effected" ("CBE") regulation, "merely permits," but does not require, a manufacturer to change its label and that 21 C.F.R. § 314.80(b) requires only review and evaluation of adverse event reports. This position is untenable in light of the Supreme Court's decision in Wyeth v. Levine, 129 S. Ct. 1187 (2009). In Wyeth, the Supreme Court recognized that 21 C.F.R. §§ 314.70 and 314.80(b) are important parts of a regulatory scheme that charges a drug manufacturer "both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." Wyeth, 129 S. Ct. at 1197-98 (citing 21 C.F.R. §§ 201.80(e), 314.70, 314.80(b)) ("[T]he CBE regulation . . . both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval.").

Although the Court takes no position on the accuracy of Dr. Parisian's conclusions, Dr. Parisian's testimony represents her qualified expert opinion about what reasonable steps drug manufacturers should take to comply with the legal duties imposed by the FDCA. This testimony is just one piece of evidence about whether Merck acted reasonably under the tort law of the State of Florida. As noted in the Court's July 2009 Daubert Opinion, "[t]he cases in this MDL are not governed by federal regulations but by state law theories of negligence and strict liability. Expert testimony on regulatory compliance will assist the jury in determining whether Merck acted as a reasonably prudent pharmaceutical manufacturer. The Court will instruct the jury that it must take the law from the Court and not from any witness." In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d at 191 n.16.

For the above reasons, Merck's motion is DENIED.

Merck's Motions in Limine # 9 & #11

In its Motion in Limine #9, Merck moves to exclude evidence of Merck's action after the onset of Graves' alleged injury. In Merck's Motion in Limine #11, Merck asks the Court to allow adverse event reports ("AERs") and case reports only to prove notice, and to exclude all AERs and case reports received by Merck after the onset of Graves' alleged injury. At oral argument, the Court granted Merck's Motion in Limine #11 in

part, and held that adverse event reports are admissible only to prove when Merck had notice of the adverse events alleged therein.

At oral argument, counsel suggested that Merck may be liable for the exacerbation of Graves' injury, making the date of injury difficult to pinpoint. In Boles I, the Court granted summary judgment to Merck on any claim that Fosamax exacerbated Mrs. Boles' ONJ because the only evidence of exacerbation--the testimony of Dr. Alistair Goss--was unreliable. In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 277 (S.D.N.Y. 2009). In the case at bar, Dr. Goss's testimony has been excluded, and Graves has put forth no evidence that Fosamax exacerbates ONJ. Therefore, any liability on Merck's part attaches as of the date of Graves' injury. In turn, the admissibility of the AERs and case reports depends on the injury date, making a firm determination of this point essential. Merck argues that AERs and other evidence of its actions after March 2003--the injury date set forth in Graves' Plaintiff Profile Form--are not relevant to Merck's liability for Graves' injury. Graves maintains that there is a factual dispute about when her injury occurred.

At first it appeared that there may be a factual dispute regarding the timing of Graves' injury. However, Graves self-reported her date of injury as "3/2003" on her Plaintiff Profile

Form, and may not depart from that statement. The Court also addresses this issue in its Opinion and Order on Merck's summary judgment and Daubert motions. Graves v. Merck, No. 1:06-cv-05513, slip op. at 8, 16-17 (S.D.N.Y. Oct. 22, 2010).

Graves may not introduce evidence of Merck's conduct after March 31, 2003 to show what Merck knew or should have known about the risks of ONJ after that date or to show the inadequacy of warnings given after that date, or any AERs or case reports received by Merck after March 31, 2003. This evidence is not relevant to establishing liability for Graves' alleged injures, and therefore, Merck's motions in limine #9 and #11 are GRANTED.

SO ORDERED.

Dated: New York, New York
October 27, 2010

JOHN F. KEENAN
United States District Judge