Fosamax and the Risk/Benefit Analysis

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As millions of aspiring witches and wizards line up for the opening of the last installment of the Harry Potter series, we bring you the latest – but likely not the final – chapter in the Fosamax litigation and specifically the twice-tried case of Boles v. Merck. We've previously discussed the disheartening events in Boles here but here is a quick recap:

- *Book 1-Fosamax and the Prisoners of the Jury Box: The Hung Jury*: jury failed to reach a verdict (7-1 in favor of defendant)
- *Book 2-Fosamax and the Closing Argument of Fire: Outrageous Misconduct:* the second trial, due to plaintiff's counsel's outrageous and unprofessional conduct, resulted in an $8 million verdict
- *Book 3-Fosamax and the Order of Remittitur:* The court denied defendant's motions for judgment as a matter of law and for a new trial but reduced the verdict to $1.5 million (by the way, plaintiff rejected the reduced verdict and requested a new trial on damages)

The stage is now set for *Book 4-Fosamax and The Half-Allowed Interlocutory Appeal*. In re Fosamax Products Liability Litigation (Boles), 2011 U.S. Dist. LEXIS 72123 (S.D.N.Y. Jun. 29, 2011). The decision being appealed can be found at In re Fosamax Products Liability Litigation, 742 F. Supp. 2d 460 (S.D.N.Y. 2010) and the single question certified for appeal is whether under Florida law:

> "a plaintiff [may] establish that a prescription drug is defective by showing that its risks outweigh its benefits for a subset of the patient population for whom the drug is indicated, regardless of the risk-benefit calculus for the indicated patient population as a whole?"

In re Fosamax, 2011 U.S. Dist. LEXIS 72123, at *26. Now the Second Circuit has to be persuaded to hear the appeal.

In the Boles II trial, plaintiff's only remaining claims were for negligent and strict liability design defect. Id. at *7. Following the verdict for plaintiff, the court held that "a jury could find in favor of Boles if the jury determined that Fosamax's risks outweigh its benefits, or lack thereof, when

used as indicated for the prevention of osteoporosis." Id. at *13 (citation and quotation marks omitted). Defendant argued that under Florida law, for plaintiff to recover for design defect, she must show that

> "the risks of a product outweigh its benefits from an objective standard--from the perspective of the population at large and not merely from the perspective of a particular user or group of users."

Id. at *15. The court, hoping that "a third Boles trial will be the final Boles trial," id. at *26, decided to seek guidance from the Second Circuit on the scope of the risk/benefit analysis. In addition to finding this to be a controlling question of law that would impact hundreds of cases pending in the Fosamax MDL involving Florida plaintiffs, the court also found it was a contestable issue because defendant's objective standard was supported by authority but was not a question on which the Florida Supreme Court had ruled. Id. at *19-20.

So, while not quite an epic battle between good and evil and certainly not this summer's biggest legal blockbuster, the continuing saga of Boles and the proper application of the risk/benefit analysis under Florida law – specific-user standard v. objective standard – is one we'll watch with keen interest.

And now, after the Supreme Court has clarified the scope of Wyeth v. Levine, 555 U.S. 555 (2009), in Pliva, Inc. v. Mensing, ___ U.S. ___, 2011 WL 2472790 (U.S. June 23, 2011), and reminded everyone that Levine turned on the difference between a prior FDA approval requirement as opposed to a mere *post facto* FDA veto (rarely, if ever, exercised), we expect to see preemption return as a defense to design-related claims where the kind of loophole to prior FDA approval does not exist. Since even the dissent in Mensing did not undertake to defend the lower court's "it's not impossible because you can just stop selling the FDA-approved drug" argument, 2011 WL 2472790, at *17 n.8, we look forward to an eventual *Book 5–Fosamax and the Chamber of Preemption*.