North America – US

# *Wyeth v Levine* reinterpreted: preemption is sometimes a question for the jury

## Introduction

### *In re: Fosamax Products Liability Litigation – F.3d*[1]

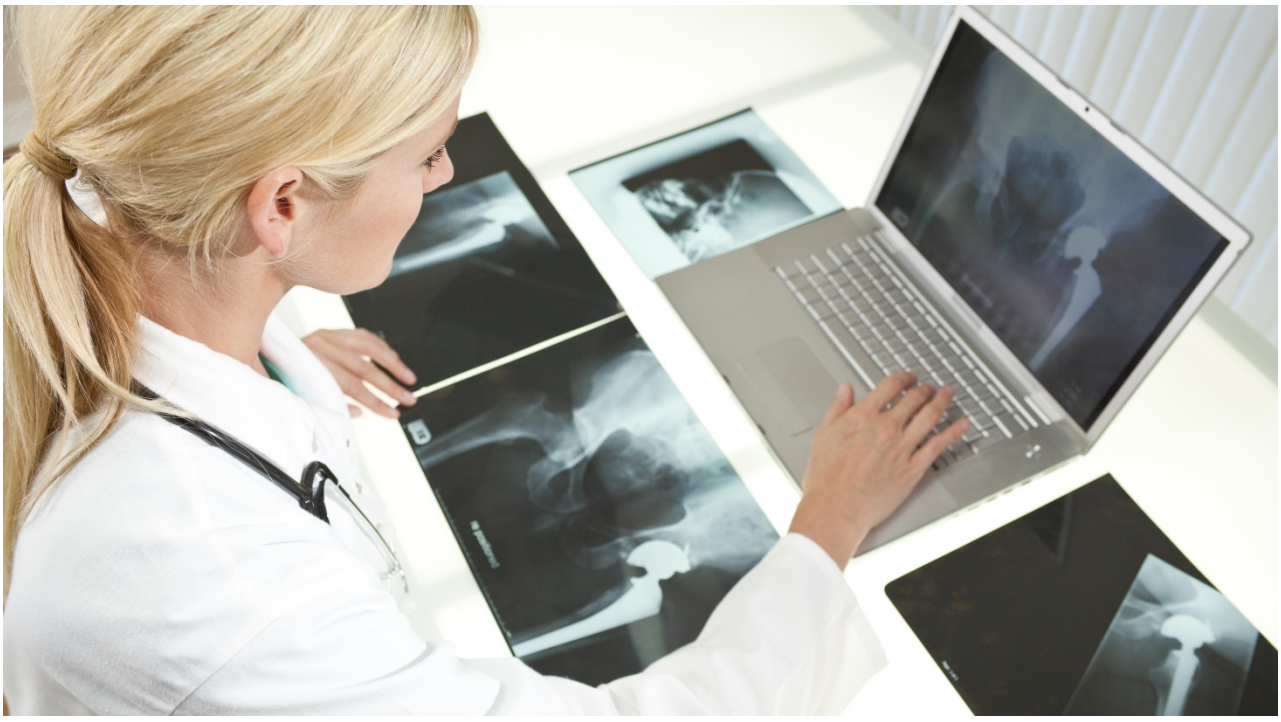
The US Circuit Court of Appeals in Philadelphia recently evaluated the appropriateness of the District Court's order granting summary judgment, on grounds of preemption, in the *Fosamax* litigation. This concerned claims by multiple plaintiffs alleging that Merck & Co failed to adequately warn about the risks of thigh-bone fractures associated with the drug Fosamax.

The primary factual inquiry at issue was whether the US Food & Drug Administration (FDA) would have approved a warning about bone fractures prior to September 2010. This was the date on which the FDA taskforce published a report finding that "there is evidence of a relationship between long-term [bisphosphonate] use and a specific type of subtrochanteric and femoral shaft fracture".

## Facts

In September 2008, while the FDA was analysing Merck's data regarding femoral fractures, Merck submitted a Prior Approval Supplement (PAS) proposing additional language to both the "Warnings & Precautions" and "Adverse Reactions" sections of the label. In May 2009, the FDA advised Merck that its PAS was not approved. During this timeframe, several informal communications between FDA physicians and Merck representatives regarding the reasoning behind the denial were recorded by memo.

It was not until September 2010 that the FDA published its report concluding that there was an association between long-term bisphosphonate use and atypical fractures. But it also concluded that the association had not been proved to be causal. In October 2010, the FDA announced that it would require the language regarding the risk of atypical femoral fractures, but emphasised that it was not clear whether bisphosphonates were the cause.



[1] 2017 WL 1075047 (3rd Cir. Mar. 22, 2017).

Merck submitted its proposed language in October 2010 and the FDA approved it in January 2011.

## Third Circuit judgment

The District Court's order granting summary judgment on the grounds of preemption was reversed. The Court considered that there was sufficient evidence for a reasonable jury to conclude that the FDA would have approved a differently worded warning about the risk of thigh fractures. Or, at the very least, a reasonable jury would conclude that the odds of FDA rejection were less than highly probable.

The Third Circuit focused its legal analysis on two questions: (1) what is "clear evidence" and (2) who should determine whether "clear evidence" exists? Ultimately, the Court found that "clear evidence" refers solely to the applicable standard of proof. The ultimate question of whether the FDA would have rejected a label change is a question of fact for the jury rather than for the court.

In so holding, the Court emphasised the ruling's limits. Specifically, the Court noted that it did not mean to suggest that summary judgment is categorically unavailable to a manufacturer asserting a preemption defence. Rather, a trial by jury is only necessary in those cases where the evidence presented is more compelling than *Wyeth* but no "smoking gun" rejection letter from the FDA is available.

The Court analysed the *Wyeth* decision and those applying it to discern the meaning of "clear evidence" in this context. It concluded that the term does not refer directly to the type of facts that a manufacturer must show. Instead, it specifies how difficult it will be for the manufacturer to convince the fact-finder that the FDA would have rejected a proposed label change. Stated differently, the manufacturer must prove that the FDA would have rejected a warning not simply by a preponderance of the evidence, but by "clear evidence".

Going back to *Wyeth*, the Court emphasised three reasons why the circumstances of this case required the jury to evaluate Merck's preemption defence

1. it required the assessment of the probability of a future event
2. both the plaintiffs and defendant asked the Court to draw competing inferences from separate pieces of the record and weigh those inferences against one another and
3. the determination involved an inquiry about motive or state of mind (ie what were FDA officials thinking, and how would that have conditioned their response to the plaintiffs' hypothetical warning?).

## Comment

The extent to which this decision may have an impact in other pharmaceutical cases will depend on whether the evidence of rejection by the FDA is so clear that the interpretation of such will not differ among jurors. Without a "smoking gun" rejection letter, other defendants may also land in front of a jury on this issue. In this case, there was enough ambiguity for the court to hold that a jury could conclude that the FDA would have approved a differently worded warning about the risk of thigh fractures. The decision presents the concern that this standard may be one that is impossible to meet. Even if the standard is met, there is a major risk of inconsistency among questions of federal preemption decided by multiple juries in multiple jurisdictions among varying types of cases.

**Sydney Fairchild**
Senior Associate,
Baltimore
sydney.fairchild@hoganlovells.com