The Supreme Court has long resolved whether and when state law claims against drug manufacturers are preempted by federal law. The Third Circuit ruling in *Merck Sharp & Dohme Corp. v. Albrecht* [2] is very favorable to state-law claims and likely will be modified, if not reversed, by the Supreme Court.

The Food and Drug Administration’s (FDA) approval of a drug warning label does not necessarily insulate drug manufacturers from state-law failure-to-warn claims. In *Wyeth v. Levine* [3] (2009), the Supreme Court held that state failure-to-warn claims are preempted when there is “clear evidence” the FDA would not have approved the warning a plaintiff claims was necessary. In *Merck Sharp & Dohme Corp. v. Albrecht* [2], Merck claims there was such “undisputed” evidence in this case but the Third Circuit improperly allowed the case go to a jury for “conjecture as to why the FDA rejected the proposed warning.”

Plaintiffs sued drug manufacturer Merck alleging that the osteoporosis drug Fosamax caused them to suffer serious thigh bone fractures. They brought state law failure-to-warn claims on the grounds that Merck had not provided adequate warnings on its label.

Merck had long made the FDA aware that Fosamax might increase the risk of atypical femoral fractures. In 2008 Merck proposed changes to the drug label regarding fractures. The FDA rejected them because “the conflicting nature of the literature does not provide a clear path forward.” The FDA also objected to the use of the imprecise term “stress fracture” in the proposed language. In 2010 an FDA task force published a report saying there was “evidence of a relationship between” Fosamax and femoral shaft fractures. The FDA then changed the label but didn’t use the word “stress fractures.” (Plaintiffs all claim they suffered bone fractures before the label change.)

Merck argues that it is “undisputed” that until 2010 the FDA would not agree to a warning about fractures. But the Third Circuit allowed a jury to decide whether the FDA would have approved the label plaintiffs wanted. According to the lower court a jury could conclude that the FDA’s rejection of Merck’s proposed changes to the warning label “were based on Merck’s misleading use of the term ‘stress fractures’ rather than any fundamental disagreement with the underlying science.”

In response, Merck argues lay juries should not be in the business of “inferring” whether the FDA objected only to Merck’s “wording.” “If a drug manufacturer candidly brings a risk to the FDA’s attention and proposes an on-point warning, the FDA’s rejection should suffice as a matter of law to preempt claims alleging failure to warn of that risk.”

More generally, Merck also assert that this is just one of a number of cases where “courts have erected a series of procedural and substantive hurdles [to the preemption defense], making it virtually impossible to establish.” Merck calls for the Supreme Court to “lay down a legal marker for when a failure-to-warn claim is properly preempted in the branded drug context, and thus revive the preemption defense that courts . . . have narrowed virtually out of existence.”

By: