LEGAL UPDATES

PUBLISHED: MAY 23, 2019

Supreme Court Reiterates that Federal Law Preemption for Product Warnings is a Matter for Judge, Not Jury

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On Monday, the United States Supreme Court found that a judge is better suited than a jury to decide if consumers' tort claims are preempted by federal regulations. In the case, *Merck Sharp & Dome, Corp. v. Albreecht*, the Supreme Court was confronted with deciding whether the U.S. Food and Drug Administration would have requested a proposed warning of the risk associated with Merck's osteoporosis drug Fosamax, a drug used to treat and prevent osteoporosis in older women.

When FDA approved Fosamax's label in 1995, the label did not include a warning about atypical femoral fractures – a warning that was added in 2010. More than 500 patients who took Fosamax before the warning was added claimed that under state law Merck had a duty to warn them to the potential femoral fractures. Merck argued that any such warning would have conflicted with FDA's approval of the drug and regulation regarding labeling and as such was federally preempted.

"[J]udges are better suited than are juries to understand and to interpret agency decisions in light of the governing statutory and regulatory context," the high court said. "To understand the question as a legal question for judges makes sense given the fact that judges are normally familiar with principles of administrative law." Specifically, judges would have to review whether there was "clear evidence" that a proposed label change would be denied by the FDA.

Contact us

The FDA team at Husch Blackwell will continue to monitor legal developments involving the impact of federal preemption arising out of FDA laws and regulations. If you have questions about the implications of the decision for your business, contact Seth Mailhot, Emily Lyons or your Husch Blackwell attorney.