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# Hughes Hubbard & Reed

## Firm Helps Win Supreme Court Hearing for Merck Over Fosamax Suits

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**July 13, 2018** — In a development that has potentially huge ramifications for Merck and the pharmaceutical industry as a whole, the firm helped Merck convince the U.S. Supreme Court that it should hear the pharmaceutical giant's appeal of a Third Circuit ruling that revived hundreds of lawsuits over Merck's alleged failure to warn about a risk of thigh bone fractures from its osteoporosis drug Fosamax.

On June 28, one month after a recommendation from the U.S. Solicitor General and the U.S. Food and Drug Administration to take the case, the high court granted review of the core ruling in these cases, which has major implications for consumers and drugmakers regarding lawsuits filed over product warnings.

The case addresses one of the most significant federal preemption issues for branded drug companies since the Supreme Court's landmark 2009 ruling in *Wyeth v Levine*. In that decision, the high court found that pharmaceutical companies can't be sued for a failure to warn where there is "clear evidence" that the FDA would not have approved a proposed label change to their products.

Merck has argued that the FDA rejected its proposal to add a warning label to Fosamax after it submitted data to the agency in 2008 suggesting that the medication might cause certain femoral fractures, and that this rejection should act to bar state court suits alleging that Merck should have revised its labels to include such a warning.

HHR has been involved with Merck's defense since shortly after hundreds of plaintiffs began filing suits against the drugmaker in 2010. The suits were eventually consolidated in a multidistrict litigation in New Jersey federal court. HHR has been involved with other Fosamax suits for years prior to the beginning of the femur litigation, including litigation involving alleged jaw injuries that was part of an MDL recently closed before Judge John F. Keenan of the U.S. District Court for the Southern District of New York.

In 2013, the firm helped Merck win a preemption motion that resulted in a landmark decision from U.S. District

Judge Joel Pisano. HHR conducted the factual investigation that formed the basis of the preemption motion, which argued that plaintiffs' failure-to-warn claims were preempted by federal law because the FDA had rejected the proposed warning label. The decision effectively ended approximately 500 remaining lawsuits until the Third Circuit revived them in March 2017, holding that the issue of whether the FDA would have allowed a different warning was one for juries to decide, not judges.

In its petition to the Supreme Court, Merck seeks to challenge the Third Circuit's determination that the drugmaker must prove to individual juries that federal regulators would not have allowed the warnings that plaintiffs claim should have been included in the prescription drug labels.

Ted Mayer, Bill Beausoleil and Jack Kilgard comprise the HHR team that is working with several other firms in defending Merck.

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**Theodore V.H. Mayer**



**William J. Beausoleil**



**John M. Kilgard**

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