
Hughes Hubbard & Reed

Hughes Hubbard Helps Merck Obtain Significant Win in Supreme Court

News & Events | Deals & Matters

Hughes Hubbard & Reed LLP • A New York Limited Liability Partnership
One Battery Park Plaza • New York, New York 10004-1482 • +1 (212) 837-6000

Attorney advertising. Readers are advised that prior results do not guarantee a similar outcome. No aspect of this advertisement has been approved by the Supreme Court of New Jersey. For information regarding the selection process of awards, please visit <https://www.hugheshubbard.com/legal-notices-methodologies>.

June 3, 2019 — Hughes Hubbard helped score a significant win for Merck & Co. when the U.S. Supreme Court ruled that a judge, rather than a jury, must determine whether federal regulators would have allowed the warnings that plaintiffs claim should have been included in labels for the osteoporosis drug Fosamax.

On May 20, a majority of five and four concurring justices agreed to reverse a decision by the U.S. Court of Appeals for the Third Circuit that revived a multidistrict litigation against Merck, and remanded the case to the lower court.

The ruling is a clear win for the pharmaceutical industry because it preserves preemption as a viable defense for manufacturers and establishes as a procedural matter that preemption issues will not go to juries, can be decided early on in litigation by judges and can have a broad impact across multiple (and potentially all) cases in a mass tort setting.

Merck argues that the U.S. Food and Drug Administration 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. Merck further argued that this rejection should bar state court failure-to-warn claims alleging that Merck should have revised its labels to include such a warning.

HHR has helped defend Merck since shortly after hundreds of plaintiffs began filing suits against the drugmaker in 2010. The suits were eventually consolidated in an MDL 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 in New York federal court.

In 2013, HHR helped Merck win a preemption motion in New Jersey federal court, resulting in a landmark decision that effectively ended approximately 500 remaining lawsuits. 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 Merck's proposal to revise its label to add additional warnings. The Third Circuit revived the lawsuits in March 2017, finding that it was unclear whether the FDA would have allowed a different warning, and that the issue was one for juries, not judges, to decide.

But the Supreme Court disagreed. "Judges are better suited than are juries to understand and to interpret agency decisions in light of the governing statutory and regulatory context," Justice Stephen Breyer wrote in the majority opinion.

The Third Circuit will now decide, according to the high court opinion, whether Merck "fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning."

The ruling elicited widespread media coverage, including in The Wall Street Journal, Bloomberg, ABCNews.com, Reuters, The National Law Journal and Law360.

Ted Mayer, Bill Beausoleil and Jack Kilgard comprise the HHR team that is working with several other firms in defending Merck. Alumna Jessica Studness played a critical part in the factual investigation.

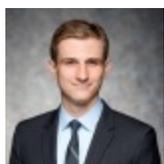
Related People



Theodore V.H. Mayer



William J. Beausoleil



John M. Kilgard

Related Areas of Focus

[Litigation](#)

[Product Liability](#)

[Appellate](#)

[Life Sciences](#)