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PRESS RELEASE

Wiley Rein *Amicus* Brief for U.S. Chamber Urges Supreme Court to Review Drug Company's Challenge to Product Liability Verdict

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Wiley Rein has filed an *amicus* brief with the Supreme Court of the United States on behalf of the U.S. Chamber of Commerce, supporting a pharmaceutical company's challenge to a multi-million-dollar jury verdict in a product liability suit.

The Massachusetts Supreme Judicial Court (SJC) erred in an April 2015 ruling that upheld the 2013 verdict, according to the U.S. Chamber's brief, filed November 9 in *Johnson & Johnson and McNeil PPC, Inc. v. Lisa Reckis and Richard Reckis*. The *amicus* brief, authored by Wiley Rein founding partner Bert W. Rein and partner Karyn K. Ablin, urges the Supreme Court to grant the drug manufacturers' petition for certiorari.

The plaintiffs claimed that their daughter's rare, life-threatening health condition was triggered by an adverse reaction to an over-the-counter medicine whose label, they alleged, did not adequately warn of the drug's potential risks. The drug manufacturers asserted that the plaintiffs' claim was preempted by federal law because the U.S. Food and Drug Administration already had considered and rejected including warning language on the label that the plaintiffs said was needed.

Wiley Rein's *amicus* brief argues that the SJC's ruling "fundamentally misunderstands" three recent Supreme Court decisions—*Wyeth v. Levine*, *PLIVA, Inc. v. Mensing*, and *Mutual Pharmaceutical Co. v. Bartlett*—regarding "the operation and preemptive effect of the

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federal drug labeling regime in state-law tort cases involving a collision between drug labeling mandated by the federal Food and Drug Administration ... and state product liability judgments premised on the failure to change that labeling."

"Drug manufacturers must use only the labeling that FDA approves," Mr. Rein and Ms. Ablin explained in the brief. "In the absence of an FDA-authorized exception permitting changes to this labeling, the Supremacy Clause forbids states from imposing labeling-based liability on manufacturers following this mandate."

The brief asks the Supreme Court to clarify the scope and operation of the Supremacy Clause under *Wyeth*, *Mensing*, and *Bartlett*; the proper bounds of an agency regulation permitting limited labeling changes prior to receiving FDA approval; and the Supreme Court's as-yet-undefined "clear evidence" test for assessing whether state tort law claims premised on inadequate drug labeling are preempted by federal law.

The *amicus* brief can be found here.