Press Release

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WLF Asks High Court to Bar State Tort Suits that Impose Liability on Drugmakers for Using Federal Warning Labels

(Johnson & Johnson v. Reckis)

"Hard cases make bad law. Juries naturally sympathize with badly injured patients, but the health care system is ill-served when lay jurors are permitted to overrule FDA's considered judgment regarding what warnings should go onto drug labels."
— Richard Samp, WLF Chief Counsel

WASHINGTON, DC—Washington Legal Foundation today filed a brief urging the U.S. Supreme Court to review and reverse a Massachusetts Supreme Judicial Court decision that upheld massive liability against a drug manufacturer for failing to include a warning on the label of a commonly used pain reliever—even though the Food and Drug Administration (FDA) rejected requests to add the same warning. WLF's *amicus* brief in *Johnson & Johnson v. Reckis* argues the lower court should have held that federal law preempted the state tort claim, because it was impossible for the drugmaker to comply simultaneously with federal and state law.

Ibuprofen is an over-the-counter (OTC) pain reliever marketed under a variety of brand names (*e.g.*, Advil, Motrin) and used by about 100 million Americans each year. Ibuprofen use is associated with an extremely rare but life-threatening skin disorder, toxic epidermal necrolysis (TEN). FDA-drafted labeling for OTC ibuprofen warns consumers to discontinue use and see a doctor if allergic reactions (such as a rash) occur, but FDA specifically rejected a request from several doctors to warn that an allergic reaction might be an early symptom of TEN and/or a "life-threatening disease." (FDA determined that such detailed, difficult-to-understand warnings should be provided to doctors only.) But in the case of a young girl who developed TEN after taking Children's Motrin, a Massachusetts jury determined that the drug manufacturer negligently failed to unilaterally add the words "life-threatening disease" to the product's label. The Massachusetts courts affirmed the verdict, and the judgment now stands at $140 million.

WLF's brief argues that because FDA rejected the identical warning, the manufacturer would have violated federal law had it added the Massachusetts warning unilaterally. WLF filed its *amicus curiae* brief on behalf of itself and the Allied Educational Foundation.

Upon filing its brief, WLF issued the following statement by Chief Counsel Richard Samp: "Hard cases make bad law. Juries naturally sympathize with badly injured patients, but the health care system is ill-served when lay jurors are permitted to overrule FDA's considered judgment regarding what warnings should go onto drug labels. Placing too many warnings on labels directed to consumers can scare them away from beneficial treatments."

WLF is a public-interest law firm and policy center that advocates against state tort judgments that undermine uniform federal regulations that promote safety and protect interstate commerce.

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