Press Release

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Massachusetts High Court Clarifies Pleading Threshold in Medical-Device Cases

(*Dunn v. Genzyme*)

"State courts evaluating state-law claims involving federally approved medical devices should follow Massachusetts's lead and insist on clear and robust pleading standards."
—Cory Andrews, WLF Vice President of Litigation

WASHINGTON, DC—The Massachusetts Supreme Judicial Court today overturned a decision that would have allowed plaintiffs to impose burdensome and costly discovery on medical-device makers for unspecified wrongdoing. The decision was a victory for Washington Legal Foundation, which filed an *amicus* brief in the case urging reversal. WLF's brief was submitted with the pro bono assistance of David Geiger, Michael Hoven, and Stephen Stich at Foley Hoag LLP.

The case arose from a lawsuit over Genzyme's Synvisc-One®, an FDA-approved injection that supplements the knee's own fluids to help lubricate the joint. While the plaintiff vaguely alleges that her Synvisc-One® injection was "defective" and violated unspecified "FDA regulations," the complaint lacks factual allegations to support either of those claims. Yet Congress, in the Medical Device Amendments to the Food, Drug, and Cosmetic Act, expressly preempted all state-law claims unless they allege violation of a specific, "parallel" requirement of federal law.

As WLF's *amicus* brief argued, the plaintiff's claims are a textbook example of inadequate pleading and should be dismissed. In today's opinion, the Massachusetts high court agreed, holding that the plaintiff's complaint "invokes no facts—regulatory, medical, or otherwise—that connect Genzyme's actions with the purported harm."

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