Press Release

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

FOR IMMEDIATE RELEASE August 25, 2020

Media Contact: Glenn Lammi | glammi@wlf.org | 202-588-0302

WLF Urges Mass. High Court to Clarify Pleading Threshold in Medical-Device Cases

(*Dunn v. Genzyme*)

> **"State courts evaluating state-law claims involving federally approved medical devices should insist on clear and exacting pleading standards."**
> —Cory Andrews, WLF Vice President of Litigation

WASHINGTON, DC—Washington Legal Foundation (WLF) today asked the Massachusetts Supreme Judicial Court to overturn a decision that would allow plaintiffs to impose burdensome and costly discovery on medical-device makers for unspecified wrongdoing.

The case arises from a lawsuit about 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 shows, the plaintiff's claims are a textbook example of inadequate pleading and should be dismissed. The complaint's allegations, even if accepted as true, fail to plausibly describe a manufacturing defect in Genzyme's product. The complaint fails even to identify the purported defect, or to explain how it was introduced into Genzyme's manufacturing process. And the plaintiff's failure-to-warn claim fails to allege any facts that make plausible a deviation from the FDA-approved label, another requirement for avoiding preemption.

WLF's brief was submitted with the *pro bono* assistance of David Geiger, Michael Hoven, and Stephen Stich at Foley Hoag LLP.

Celebrating its 43rd year, WLF is America's premier public-interest law firm and policy center advocating for free-market principles, limited government, individual liberty, and the rule of law.

###