Press Release

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WLF Urges High Court to Bar False Claims Act Liability for Non-Material Regulatory Violations

(Gilead Sciences, Inc. v. U.S. ex rel. Campie)

> **"The False Claims Act is intended to root out actual fraud against the federal government, not to police compliance with every regulatory requirement imposed on a government contractor. If noncompliance is not 'material' to the government's decision to pay a claim, the plaintiffs' bar should not be permitted to transform a minor breach of contract into a fraud claim."**
> **—Richard Samp, WLF Chief Counsel**

WASHINGTON, DC—The Washington Legal Foundation late Friday urged the U.S. Supreme Court to review (and ultimately overturn) an appeals court decision that authorizes private individuals to sue pharmaceutical manufacturers for government-contracting fraud based on technical violations of federal regulations—even if the FDA approved the drugs and if government officials continued to purchase them after investigating the fraud allegations. In a brief filed in *Gilead Sciences, Inc. v. U.S. ex rel. Campie*, WLF argues that the appeals court's decision conflicts with Supreme Court precedent and facilitates the filing of unwarranted fraud claims against government contractors.

The False Claims Act (FCA) includes a unique *qui tam* provision that authorizes an individual (known as a "relator") to file suit in the name of the United States against contractors he believes have defrauded the government. Prevailing relators are entitled to share in up to 30% of any recovery, plus attorneys' fees. The relator in this case, after being fired by a Gilead, alleged to the federal government that the company was out of compliance with FDA drug-manufacturing regulations. Government officials investigated the allegations but took no action. Indeed, the drugs in question remain FDA-approved, and the government continues to pay billions of dollars each year to purchase the drugs.

The appeals court nonetheless reinstated the relator's FCA lawsuit, finding that he had adequately alleged that the drug company defrauded the government by submitting claims for payment without informing the purchaser of its regulatory noncompliance. WLF argues that the relator has failed to demonstrate that the alleged false claims are "material"—*i.e.,* that the government would not have paid the claims had it been aware of the violations. The government's response after the relator submitted his allegations demonstrates that it found the regulatory infractions had no impact on the drugs' safety or efficacy.

Celebrating its 41st 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.

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