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COURT URGED TO DISMISS FCA SUIT THAT THREATENS TO CHILL SPEECH

(U.S. ex rel. Rost v. Pfizer)

The Washington Legal Foundation (WLF) this week urged the U.S. District Court for the District of Massachusetts to rein in use of the federal False Claims Act (FCA) as a tool for suppressing truthful speech about off-label uses of medical products approved by the Food and Drug Administration (FDA).

In a brief filed in *U.S. ex rel Rost v. Pfizer, Inc.*, WLF argued that the FCA was intended as a means of preventing fraud against the U.S. government, not as a means of suppressing truthful speech. WLF argued that in the absence of specific factual allegations that a drug manufacturer took steps to encourage others to seek federal reimbursement for drug costs the manufacturer knew were not reimbursable, a complaint is subject to dismissal.

"WLF is concerned that the plaintiff's lawsuit, if allowed to proceed, could harm public health by reducing public knowledge regarding beneficial off-label uses of FDA-approved products," said WLF Chief Counsel Richard Samp after filing WLF's brief. "In opposing dismissal, the plaintiff focuses on allegations that the defendant drug manufacturers engaged in improper promotional activities. But the issue in the case is whether the defendants violated the FCA, not whether they promoted their products in a manner frowned upon by FDA," Samp said.

Pharmacia Corp. (later acquired by Pfizer, Inc) is the manufacturer of Genotropin, a synthetic human growth hormone. Plaintiff Peter Rost is a former Pharmacia employee. He filed suit under the FCA, alleging that Pharmacia/Pfizer defrauded the federal government by improperly promoting Genotropin for off-label uses (*i.e.*, uses not listed on the FDA-approved labeling), and that this activity "caused" others to prescribe Genotropin for off-label uses and to seek federal reimbursement for the costs of the drug. (The FCA permits individuals to sue in the name of the United States, to recover funds paid by the federal government on the basis of false claims. If any funds are recovered, the FCA plaintiffs are entitled to receive a portion of the proceeds.) Rost alleges that the claims submitted in connection with such off-label prescriptions were "false" because such prescriptions were not reimbursable under federal Medicare and Medicaid law.

Defendants have moved to dismiss the complaint, both for failure to state a claim (under Fed.R.Civ.P. 12(b)(6)) and for failure to plead fraud with particularity (under Fed.R.Civ.P. 9(b)). WLF filed its brief in support of that motion.

WLF argued that Rost failed to establish any causal connection between Defendants' promotional activities and the submission of any false claims. WLF noted that there is no evidence that Defendants ever took steps to encourage anyone to submit a reimbursement claim to the federal government for an off-label Genotropin prescription. WLF argued that even if Rost could show that some individuals sought such reimbursement, he cannot show that it was Pharmacia that caused them to do so -- particularly given that there are numerous sources of information (such as peer-reviewed medical journal articles) that might prompt a doctor to prescribe a medication for an off-label use.

WLF also argued that Rost had not adequately alleged scienter -- *i.e.*, that reimbursement claims were submitted with knowledge that they were false, or with reckless disregard as to their falsity. WLF argued that there is substantial basis for claiming that the off-label use on which Rost focuses -- prescribing Genotropin to treat "short stature" among adolescents -- is properly reimbursable under Medicaid and other federal health programs. WLF argued that because Rost has, at most, demonstrated that there exists a good-faith disagreement regarding reimbursability, Rost has not demonstrated that the Defendants acted with knowledge that the claims were false (*i.e.*, that the claims were not properly reimbursable).

WLF is a public interest law and policy center with supporters in all 50 States. WLF regularly appears before federal and state courts to promote economic liberty and a limited and accountable government. WLF successfully challenged the constitutionality of certain FDA restrictions on speech about off-label uses and has in place a permanent injunction against enforcement of those restrictions.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's brief is posted on WLF's web site, www.wlf.org.