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COURT URGED TO DISMISS FCA SUIT THAT THREATENS TO CHILL SPEECH

(U.S. ex rel. Hopper v. Solvay Pharmaceuticals, Inc.)

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the Eleventh Circuit 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 Hopper v. Solvay Pharmaceuticals, 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 urging reinstatement of their suit, the plaintiffs focus on allegations that the defendant drug manufacturer engaged in improper promotional activities. But the issue in the case is whether the defendant violated the FCA, not whether it promoted its products in a manner frowned upon by FDA," Samp said.

Solvay Pharmaceuticals, Inc. is the manufacturer of Marinol, a drug approved by FDA for treatment of nausea associated with chemotherapy and for treatment of anorexia associated with weight loss in AIDS patients. The plaintiffs are former Solvay employees. They filed suit under the FCA, alleging that Solvay defrauded the federal government by improperly promoting Marinol for off-label uses (*i.e.*, uses not listed on the FDA-approved labeling), and that this activity "caused" others to prescribe Marinol 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.) The plaintiffs allege that the claims submitted in connection with such off-label prescriptions were "false" because such prescriptions were not reimbursable under federal Medicaid law.

A federal district court in Florida dismissed the complaint for failure to state a claim with the particularity required in fraud cases by Fed.R.Civ.P. 9(b). The plaintiffs have appealed that dismissal. WLF's brief urges that the district court's dismissal be affirmed.

WLF's brief argues that the plaintiff's complaint failed to establish any causal connection between Solvay's promotional activities and the submission of any false claims. WLF noted that there is no evidence that Solvay ever took steps to encourage anyone to submit a reimbursement claim to the federal government for an off-label Marinol prescription.

WLF also argued that an FCA plaintiff does not meet the exacting pleadings standards of Rule 9(b) unless the plaintiff provides specific examples of false claims being submitted to the federal government. WLF noted that the plaintiffs' complaint says nothing about who made the allegedly false claims (presumably, some unspecified doctor, hospital, or pharmacy), when they were made, the substance of the claims, or whether those claims were ever paid by federal officials. Merely alleging, without providing specifics, that it is likely that someone -- in response to Solvay's promotional activities -- improperly sought reimbursement for an off-label use of Marinol that was not covered by Medicaid, is not sufficient to meet the Rule 9(b) pleadings standards, WLF argued.

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.