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FOR IMMEDIATE RELEASE **November 21, 2005**

WLF CALLS ON OCBQ TO WITHDRAW WARNING LETTER ON THROMBIN

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) today called on OCBQ (FDA's Office of Compliance and Biologics Quality) to withdraw a warning letter sent to GenTrac, Inc. on November 1, 2005 regarding GenTrac's allegedly improper promotion of Thrombin, a biologic used to stop bleeding. WLF's letter to OCBQ alleged that OCBQ lacks any basis for its claim that the risk disclosures in a GenTrac video are inadequate.

WLF's letter was sent in connection with WLF's recently inaugurated "DDMAC Watch" program. DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") regulates promotion of drugs; OCBQ does the same for biologics. WLF has determined that DDMAC and OCBQ have been using letters to industry to advance questionable legal theories and request remedial actions that the agency could not require under the law. Under the DDMAC Watch program, when DDMAC or OCBQ sends a letter to a regulated company employing theories that are legally deficient or ill-advised, WLF sends a letter of our own back to DDMAC/OCBQ identifying the specific ways in which this is so.

OCBQ's letter to GenTrac alleged that the company's video promoting Thrombin violated federal drug laws because it did not contain sufficient risk disclosure information. WLF's response challenged that assertion, noting that the video explicitly warned of the risk of death if Thrombin is misused. WLF argued that OCBQ's policy on risk disclosure is inconsistent with the policy of other FDA offices, which generally do not require disclosure of "sensitivity reactions" in the main body of a promotional piece. WLF called on OCBQ to cease sending such letters until FDA lays out a clear policy regarding what "fair balance" in advertising requires.

WLF is a public interest law and policy center with supporters in all 50 states. WLF for many years has been actively involved in efforts to decrease federal government restrictions on the flow of truthful information about FDA-approved drugs and medical devices, and to limit the circumstances under which the government may compel individuals and companies to speak against their will.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's letter will soon be posted on its web site, www.wlf.org.