

**FOR IMMEDIATE RELEASE****July 27, 2005**

WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON TRACLEER (*"DDMAC Watch" Program*)

The Washington Legal Foundation (WLF) today called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a warning letter sent to Actelion Pharmaceuticals US, Inc. (Actelion) on July 20, 2005 regarding Actelion's allegedly improper promotion of Tracleer on Actelion's web site. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate in that FDA has never issued any guidance on internet promotion of prescription drugs, despite its promises to do so.

WLF's letter was sent in connection with WLF's recently inaugurated "DDMAC Watch" program. WLF has determined that DDMAC has 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 sends a letter to a drug company employing theories that are legally deficient or ill-advised, WLF sends a letter of our own back to DDMAC identifying the specific ways in which this is so.

DDMAC's letter to Actelion alleged that Actelion violated federal drug laws by including information on its website about Tracleer, a drug used to treat pulmonary arterial hypertension. DDMAC alleged that the web site lacked risk information about Tracleer. WLF's response took particular issue with DDMAC's assertion that Actelion should have submitted the promotional material to FDA before posting it on the Internet; WLF argued that DDMAC lacks statutory authority to impose that requirement, and that it constitutes an unconstitutional prior restraint on speech.

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.