

**FOR IMMEDIATE RELEASE****October 3, 2005**

WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON CALCITRIOL (*"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 Nephrx, LLC on September 30, 2005 regarding Nephrx's allegedly improper promotion of Calcitriol on Nephrx's web site and in print advertisements. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate in that Nephrx's advertisements adequately disclosed all risks associated with use of Calcitriol.

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 Nephrx alleged that Nephrx violated federal drug laws by disseminating print advertising and including information on its web site about Nephrx, a drug used to treat hypocalcemia in patients undergoing chronic renal dialysis. DDMAC alleged that the advertisement and web site lacked risk information about Calcitriol, and made unsubstantiated superiority claims. WLF's response took particular issue with DDMAC's demand that Nephrx disseminate "corrective" promotional messages; WLF noted that FDA lacks statutory authority to require "corrective" messages, and that in any event such a demand violates the First Amendment.

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.