News Release

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FOR IMMEDIATE RELEASE **July 19, 2005**

WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON FUZEON

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) today called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a letter sent to Hoffman-LaRoche, Inc. (HLI) on July 15, 2005 regarding HRI's allegedly improper promotion of Fuzeon -- based on oral statements made by an HLR sales representative at a scientific conference. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate because FDA has never issued any guidance on oral statements by sales representatives, and because DDMAC's lacks legal authority over oral statements.

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 alleged that HRI violated federal drug laws because its sales representative discussed indications for Fuzeon not included on the product labeling. Fuzeon is a drug used for treatment of HIV-1 infection. DDMAC alleged that the representative's statements had the effect of broadening Fuzeon's indications, thereby causing the product to lack adequate directions for the use recommended by the statements. WLF's letter to DDMAC alleged that DDMAC lacks legal authority over oral statements, and has not issued any guidance on the issue. WLF also faulted DDMAC for failing to make any effort to demonstrate that what the sales representative said was inaccurate.

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.