

**FOR IMMEDIATE RELEASE****August 4, 2006**

WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON ALIMTA (*"DDMAC Watch" Program*)

The Washington Legal Foundation (WLF) yesterday called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a letter sent to Eli Lilly and Co. on July 27, 2006 regarding Lilly's allegedly improper promotion of Alimta. DDMAC alleged that a patient brochure for Alimta was false and misleading because it failed to include sufficient information regarding product risks and approved uses. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate because Lilly included detailed risk information in the prescribing information that accompanied the brochure; WLF said that there is no requirement that a manufacturer include risk information twice in its promotional material.

WLF's letter was sent in connection with WLF's "DDMAC Watch" program, which recently observed its first anniversary. 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 Lilly violated drug laws by distributing a patient brochure for Alimta, a drug approved by FDA for treating mesothelioma (a deadly form of cancer associated with exposure to asbestos) and non-small cell lung cancer. WLF's response took particular issue with DDMAC's conclusion that the brochure might mislead patients regarding Alimta's approved uses, given that the brochure makes no claims regarding uses not approved by FDA and DDMAC collected no survey data indicating that any patients had actually been misled.

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.