



FOR IMMEDIATE RELEASE

June 30, 2005

WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON LIDODERM

("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 it sent to Endo Pharmaceuticals, Inc. on June 28, 2005 regarding Endo's allegedly improper promotion of Lidoderm. WLF's letter to DDMAC alleged that DDMAC's actions violated the First Amendment, made questionable allegations regarding "minimizing" of risk information, and made inappropriate use of Endo's "regulatory history."

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 Endo alleged that Endo violated federal drug laws by disseminating direct mail pieces regarding Lidoderm, a topical anesthetic patch used for pain relief. WLF's response took particular issue with DDMAC's demand that Endo cease disseminating clinical data regarding Lidoderm that was published in a reputable, peer-reviewed medical journal. WLF alleged that DDMAC's efforts to suppress this data violate 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.