News Release

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FOR IMMEDIATE RELEASE **October 16, 2007**

WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON CYMBALTA

("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. ("Lilly) regarding Lilly's allegedly improper promotion of Cymbalta. DDMAC alleged that a professional mailer for the drug was false and misleading because it omitted important risk information for Cymbalta and overstated its efficacy. WLF's letter to DDMAC alleged that DDMAC's action was inappropriate, because the promotional material adequately disclosed the drug's recognized risks; WLF alleged that DDMAC is acting inappropriately when it insists that risk information be listed *twice* in the same advertisement.

WLF's letter was sent in connection with WLF's "DDMAC Watch" program, which WLF inaugurated in June 2005. 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 federal drug laws by releasing its promotional materials for Cymbalta, a drug approved by FDA for treating a variety of conditions, including depression, anxiety disorder, and pain management. WLF's response took particular issue with DDMAC's assertion that the materials included an unsubstantiated claim. The claim in question -- that those treated with Cymbalta experience significantly less pain interference with overall functioning -- was based on several thorough studies conducted by Lilly. FDA was critical of the methodology of the studies. WLF responded that the First Amendment does not permit FDA to ban all discussion of the studies; at most, FDA can require Lilly to include additional disclaimers that point out potential shortcomings in the studies.

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 government restrictions on the flow of truthful information about FDA-approved drugs and medical devices.

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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.