News Release

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WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON GLIADEL WAFER

("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 MGI PHARMA, Inc. on January 29 regarding MGI's allegedly improper promotion of Gliadel Wafer. DDMAC alleged that a journal advertisement for the drug was false and misleading because it failed to disclose the "full indication" for Gliadel Wafer and presented unsubstantiated claims for the drug. WLF's letter to DDMAC alleged that DDMAC's action was inappropriate, because the ad adequately disclosed the drug's approved uses, and all claims made in the ad were substantiated.

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 MGI violated federal drug laws by publishing its ad for Gliadel Wafer, a drug approved for treatment of high-grade malignant gliomas after a tumor is removed. WLF's response took particular issue with DDMAC's assertion that the ad included an unsubstantiated claim. The claim in question -- that Gliadel Wafer can begin working earlier than chemotherapy -- is substantiated by well-conducted animal studies. WLF argued that the First Amendment prohibits FDA from barring all mention of animal studies, particularly where (as here) a disclaimer could eliminate any possibility that doctors reading the ad could be misled, WLF argued.

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.