News Release

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WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON GASTROVIEW

("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 Mallinckrodt, Inc. on October 13 regarding Mallinckrodt's allegedly improper promotion of two drugs: Gastroview and OptiMARK. DDMAC alleged that exhibit booth panels for the drugs were false and misleading because they failed to provide information regarding risks associated with use of Gastroview and OptiMARK. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate, in large part because the exhibit booth panels clearly stated that company officials in the booth were available to provide full risk information. WLF argued that the availability of a company representative in the immediate vicinity provided adequate access to all risk information and ensured that no one would be misled regarding risks.

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 Mallinckrodt violated drug laws in connection with promotion of Gastroview (a drug for use in connection with x-rays of the gastrointestinal tract) and OptiMARK (an injection for use with MRIs in certain patients). WLF's response also argued that DDMAC improperly labeled Mallinckrodt a repeat offender. WLF noted that the prior letter cited by DDMAC (a February 2006 untitled regarding promotion of Neutrospec) made no allegations of improper promotion by Malllinckodt; rather, it was directed at the activities of an unrelated company.

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.