News Release

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WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON INFERGEN

("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 Intermune, Inc. on March 28, 2006 regarding Intermune's allegedly improper promotion of Infergen. DDMAC alleged that a journal advertisement for Infergen was false and misleading because it reported on a peer-reviewed study published in a reputable journal but failed to provide additional relevant information uncovered after the study was completed. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate because FDA does not challenge the legitimacy of the reported study and has stated in other contexts that manufacturers are *prohibited* from including the type of additional information that DDMAC now says should have been included.

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 alleged that Intermune violated drug laws by publishing a journal advertisement for Infergen, a drug approved by FDA for treating chronic HCV infection. WLF's response took particular issue with DDMAC's conclusion that the advertisement was deficient in failing to include medical information that has never been approved for inclusion on Infergen's labeling. WLF charged that FDA apparently *prohibits* inclusion of such information if it would make patients more likely to take the drug, but *requires* inclusion of information that would make patients less likely to take the drug.

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.