

**FOR IMMEDIATE RELEASE****June 30, 2005**

WLF CALLS ON OCBQ TO WITHDRAW WARNING LETTER ON FLUMIST (*"DDMAC Watch" Program*)

The Washington Legal Foundation (WLF) today called on OCBQ (FDA's Office of Compliance and Biologics Quality") to withdraw a warning letter sent to MedImmune Vaccines, Inc. on June 21, 2005 regarding MedImmune's allegedly improper promotion of FluMist, an influenza vaccine. WLF's letter to OCBQ alleged that OCBQ lacks any basis for its claim that the risk disclosures in MedImmune's flyers are "misleading."

WLF's letter was sent in connection with WLF's recently inaugurated "DDMAC Watch" program. DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") regulates promotion of drugs; OCBQ does the same for biologics. WLF has determined that DDMAC and OCBQ have 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 or OCBQ sends a letter to a regulated company employing theories that are legally deficient or ill-advised, WLF sends a letter of our own back to DDMAC/OCBQ identifying the specific ways in which this is so.

OCBQ's letter to MedImmune alleged that one of the company's direct-to-consumer promotional labeling pieces for FluMist violated federal drug laws because it did not contain sufficient risk disclosure information. WLF's response charged that OCBQ lacks any statutory or constitutional basis for its allegation in the absence of any evidence that some consumers have been misled by the promotional piece.

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.

* * *

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.