

**FOR IMMEDIATE RELEASE****February 10, 2006**

WLF CALLS ON OCBQ TO WITHDRAW UNTITLED LETTER ON RHOPHYLIC (*"DDMAC Watch" Program*)

The Washington Legal Foundation (WLF) today called on OCBQ (FDA's Office of Compliance and Biologics Quality) to withdraw an untitled letter sent to ZLB Behring LLC on February 3, 2005 regarding ZLB Behring's allegedly improper promotion of Rhophylac, a biologic used to suppress Rh isoimmunization in certain pregnant women. WLF's letter to OCBQ alleged that OCBQ lacks any basis for its allegation that ZLB Behring's superiority claims are unsubstantiated.

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 alleged that ZLB Behring acted improperly by distributing a professional sales aid claiming that Rhophylac was superior to competing products; OCBQ said that it was unaware of well-controlled clinical investigations substantiating such a claim. WLF argued that FDA's insistence on "well-controlled" studies before permitting comparative claims violates both federal administrative law (because FDA failed to follow requisite notice-and-comment procedures before adopting that rule) and the First Amendment. WLF argued that FDA may not completely bar claims based on the findings of less rigorous studies; rather, if there is support for the superiority claims, FDA may do no more than require that disclaimers accompany the claims.

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.