News Release

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WLF CALLS ON OCBQ TO WITHDRAW UNTITLED LETTER ON REFACTO

("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 Wyeth Pharmaceuticals, Inc. on April 13, 2006 regarding Wyeth's allegedly improper promotion of ReFacto. WLF's letter to OCBQ charged that OCBQ lacks any basis for its allegation that Wyeth made unsubstantiated safety claims regarding ReFacto.

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 a consumer-directed brochure distributed by Wyeth made unsubstantiated safety claims regarding ReFacto, a biological product approved by FDA to control bleeding and for use during surgery for patients suffering from hemophilia. OCBQ alleged that Wyeth had failed to substantiate claims that ReFacto was manufactured in such a way as to reduce danger from prions. WLF's response argued that Wyeth's safety claims were consistent with ReFacto's FDA-approved labeling, that OCBQ had no basis for rejecting the studies upon which Wyeth based its safety claims, and that OCBQ had failed to provide any empirical basis for concluding that anyone was misled by Wyeth's brochure.

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.