News Release

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FOR IMMEDIATE RELEASE **February 10, 2006**

WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON ZEVALIN

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) today called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a letter sent to Biogen Idec Inc. on December 15, 2005 regarding Biogen Idec's allegedly improper promotion of Zevalin. DDMAC alleged that a brochure for Zevalin, which focused on reimbursement issues, was false and misleading because it omitted important risk information regarding the biological product. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate because a brochure designed to facilitate reimbursement of purchase costs should not be subject to the same "risk disclosure" standards as product labeling. WLF also criticized DDMAC for waiting nearly two months – until early February – to publicly release its letter to Biogen Idec.

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 Biogen Idec violated federal drug laws by distributing, at a June 2005 meeting of the American Society of Health System Pharmacists, a brochure explaining to pharmacists how to obtain reimbursement for Zevalin -- a biological product approved for treatment of some forms of non-Hodgkin's lymphoma. WLF's response took particular issue with DDMAC's conclusion that the brochure was deficient even though it referenced the accompanying "package insert," a document that provided detailed explanations of the risks of using Zevalin.

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.