

**FOR IMMEDIATE RELEASE****July 21, 2005**

## **WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON SURVANTA (*"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 Abbott Laboratories (Abbott) on July 15, 2005 regarding Abbott's allegedly improper promotion of Survanta -- based on Abbott's distribution of a professional direct mailer regarding the drug. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate because FDA has never issued any guidance on the prominence that must be given in such mailers to risk information, and that its efforts to suppress truthful speech violated the First Amendment.

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 Abbott violated federal drug laws by disseminating direct mailers regarding Survanta, a drug used to prevent and treat Respiratory Distress Syndrome in premature infants. WLF's response took particular issue with DDMAC's demand that Abbott cease disseminating clinical data regarding Survanta that was published in a reputable journal. WLF alleged that DDMAC's efforts to suppress this data violate the First Amendment. WLF called on DDMAC, before sending further letters alleging that manufacturers give greater prominence to risk information, to provide some sort of guidance to industry on the matter.

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](http://www.wlf.org).