News Release

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WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTERS ON HYDASE, ZOVIRAX

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) this week called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw warning letters sent to PrimaPharm, Inc. on June 29, 2006 (regarding PrimaPharm's allegedly improper promotion of Hydase), and to GlaxoSmithKline (GSK) on June 30, 2006 (regarding GSK's allegedly improper promotion of Zovirax). DDMAC alleged that a sales aid for Hydase was misleading because it failed to disclose all risk information. DDMAC alleged that material regarding Zovirax on GSK's website was misleading because it overstated Zovirax's efficacy and omitted risk information. WLF's letter to DDMAC alleged that both DDMAC letters were inappropriate because they characterized promotional materials as misleading without a sufficient empirical basis and faulted GSK for citing clinical studies whose accuracy DDMAC has no basis for challenging.

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 June 30 letter alleged that GSK's promotional material might lead readers to believe (falsely) that Zovirax, an ointment approved by FDA for treating genital herpes, had been approved to prevent transmission of herpes. WLF responded that DDMAC's actions run afoul of the First Amendment. WLF charged that before government may take action with respect to an omission that allegedly renders an advertisement misleading, it must develop data demonstrating that the omission has, in fact, misled consumers. WLF charged that DDMAC sent its letter without even alleging that anyone was misled; rather, DDMAC is simply fearful that someone *might* be misled. The First Amendment does not permit censorship based solely on such unsubstantiated fears, WLF charged.

DDMAC's June 29 letter alleged that PrimaPharm's sales aid failed to provide risk information for Hydrase, approved for use as an adjuvant to increase the absorption and dispersion of other injected drugs. WLF responded that PrimaPharm adequately provided risk information when it printed the full FDA-approved prescribing information on the back of the sales aid. WLF charged that DDMAC's insistence that a manufacturer repeat that same risk information in the "creative" portion of its promotional material is not authorized under FDA regulations and cuts against FDA's ongoing initiatives to cut down on the total amount of risk information conveyed so that consumers can focus more easily on the most important risks.

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.