News Release

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WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON VITRASE

("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 ISTA Pharmaceuticals, Inc. on November 2 regarding ISTA's allegedly improper promotion of Vitrase. DDMAC alleged that a journal advertisement for Vitrase was false and misleading because it omitted important risk information regarding the drug. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate because ISTA included all the necessary risk information in the "brief summary" portion of its advertisement. WLF argued that there is no requirement that a drug manufacturer repeat that same risk information in the "creative" portion of its advertisements.

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 ISTA violated federal drug laws by running an ad for Vitrase, a drug used as an adjuvant to increase the absorption and dispersion of other injected drugs. WLF's response took particular issue with DDMAC's efforts to adopt a new rule on risk disclosure without following administrative protocol for adopting new rules. WLF argued that if DDMAC wishes to adopt a new rule stating that it is no longer sufficient to include risk information in the "brief summary," it may do so only after following notice-and-comment rulemaking procedures mandated by federal law.

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.