News Release

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WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON ACULAR LS

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) today called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a warning letter sent to Allergan, Inc. on May 25 regarding Allergan's allegedly improper promotion of Acular LS in connection with a professional journal advertisement. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate in that FDA faulted Allergan for broadening the drug's indication and making "unsubstantiated superiority claims" without having any evidentiary support for asserting that Allergan's advertisement actually made the claims DDMAC alleged.

WLF's letter was sent in connection with WLF's "DDMAC Watch" program, which will soon be marking its second anniversary. 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 to Allergan alleged that Allergan violated federal drug laws by improperly promoting Acular LS, an ophthalmic solution approved for treating ocular pain following corneal refractive surgery. WLF's response stated that a fair reading of the advertisement makes clear that Allergan was not claiming that Acular LS had been approved by FDA for any other uses. WLF also charged that DDMAC is violating Allergan's First Amendment rights by rejecting Allergan's right to present truthful information about its product so long as it is accompanied by appropriate disclaimers. DDMAC takes the position, contrary to established case law, that product information not approved by FDA may not be included in professional journal advertisements, no matter how extensive the disclaimers that accompany the information.

WLF is a public interest law and policy center with supporters in all 50 states. WLF has been actively involved in efforts to decrease federal government restrictions on the flow of truthful information about FDA-approved drugs and medical devices.

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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.