



FOR IMMEDIATE RELEASE

September 14, 2006

WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON PROGRAF ("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 Astellas Pharma US, Inc. on August 31 regarding Astellas's allegedly improper promotion of Prograf. DDMAC alleged that a professional journal advertisement for Prograf was false and misleading because it made unsubstantiated superiority claims and minimized risks associated with Prograf. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate because Astellas's claims were fully substantiated: they were based on a peer-reviewed study published in a leading medical journal.

WLF's letter was sent in connection with WLF's "DDMAC Watch" program, which recently observed its first 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 alleged that Astellas violated drug laws by distributing an advertisement for Prograf, a drug approved by FDA for combating organ rejection among patients receiving liver or kidney transplants. WLF's response noted that although DDMAC apparently disagreed with the conclusion of the author of the peer-reviewed study that Prograf was demonstrably superior to alternative treatments, FDA has actually accepted the study for inclusion in the approved product labeling for Prograf.

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.