News Release

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WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON BENICAR

("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 Sankyo Pharma Inc. on January 6 regarding Sankyo's allegedly improper promotion of Benicar in connection with a sales aid it distributed. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate in that FDA faulted Sankyo for making "unsubstantiated effectiveness and superiority claims" for Benicar even though Sankyo cited articles from reputable medical journals to support its claims, and FDA has yet to issue any guidance on making comparative claims.

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 to Sankyo alleged that Sankyo violated federal drug laws by improperly promoting Benicar and Benicar HCT, which are angiotensin II receptor antagonists approved by FDA for treating hypertension. DDMAC alleged that in making its superiority claims, Sankyo relied on studies that FDA did not deem "well-controlled." WLF's response charged that FDA is violating the First Amendment in attempting to prohibit all mention of the studies, whose truthfulness FDA does not challenge. At most, FDA may require a manufacturer that cites truthful information from reputable journals to include disclaimers pointing out potential shortcomings in the studies, WLF said. WLF took particular issue with DDMAC's demand that Sankyo disseminate "corrective" promotional messages; WLF noted that FDA lacks statutory authority to require "corrective" messages, and that in any event such a demand violates the First Amendment.

WLF's letter noted that it has pointed out similar deficiencies in prior warning letters sent out by DDMAC, but that DDMAC has persisted in making the same statutory and constitutional errors and has not even responded to WLF letters. WLF said that that pattern indicates that FDA has established its lawless letter-writing practices as official agency policy.

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.