News Release

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WLF CALLS ON DDMAC TO WITHDRAW LETTERS ON DYRENIUM AND EVOXAC

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) yesterday called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw an untitled letter sent to WellSpring Pharmaceutical Corp. on December 19, 2006 (regarding WellSpring's allegedly improper promotion of Dyrenium) and a warning letter sent to Daiichi Sankyo, Inc. (DSI) on January 12, 2007 (regarding DSI's allegedly improper promotion of Evoxac. DDMAC alleged a professional print advertisement for Dyrenium and a wall calendar for Evoxac were false and misleading because they failed to disclose all risk information and (in the case of Dyrenium) made unsubstantiated superiority claims. WLF's letter to DDMAC alleged that both of DDMAC's letters were inappropriate, because they required "double disclosure" of risk information, characterized promotional materials as misleading without a sufficient empirical basis, and inappropriately devalued a clinical study.

WLF's letters were sent in connection with WLF's "DDMAC Watch" program, which WLF inaugurated in June 2005. WLF has determined that DDMAC has been using letters to the 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 December 19 letter alleged that WellSpring's advertisement overstated efficacy claims for Dyrenium, which is approved for treatment of edema in a variety of settings, and made unsubstantiated superiority claims. WLF responded that DDMAC lacked any empirical basis for asserting that readers of the ad would think that WellSpring was making the alleged efficacy claim, and that nothing in the ad's language readily indicated that WellSpring was making such a claim. WLF also responded that DDMAC may not prohibit *all* references to clinical studies that conclude that the drug is superior to alternatives; if FDA does not like the study design, it should simply require the ad to mention any potential shortcomings in the study.

DDMAC's January 12 letter faulted DSI's wall calendar for Evoxac, a drug used to treat symptoms of dry mouth in certain patients, because the risks of taking the drug were

inadequately displayed -- they were on the back of the calendar. WLF responded that DDMAC's "double disclosure" requirement (requiring that risk information be included both in the detailed "brief summary" portion of the promotional material and in the main body of the ad) is consistent neither with the First Amendment nor with federal statutes. WLF argued that it should be sufficient to reference in the main body of an ad a location to which readers can readily turn to find detailed risk information. WLF argued that requiring too much risk information on an advertisement tends to distract readers from the most important safety considerations for that drug.

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 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.