News Release

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WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTER ON ORAPRED

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) this week called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw a letter sent to BioMarin Pharmaceuticals, Inc. on October 11 regarding BioMarin's allegedly improper promotion of Orapred. DDMAC alleged that promotional material on a product website was false and misleading because it failed to provide information regarding risks associated with use of Orapred and improperly broadened the product's indicated uses. WLF's letter to DDMAC alleged that DDMAC's actions were inappropriate, in large part because the website included all FDA-required risk information. DDMAC's only complaint was that BioMarin failed to include risk information on *every page* of the website.

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 BioMarin violated drug laws by sponsoring promotional material on a website for Orapred, a drug approved by FDA for treatment of allergies and respiratory diseases. WLF's response noted that DDMAC has never issued any specific guidance document on internet promotions of prescription drugs, despite many promises to do so and despite a 2001 WLF Citizen Petition pointing out the absence of such guidance. WLF argued that DDMAC should refrain from issuing any more warning letters regarding web sites until after it provides appropriate guidance.

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.