News Release

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WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTER ON NATRECOR

("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 Scios Inc. regarding Scios's allegedly improper promotion of Natrecor. DDMAC alleged that a mouse pad and pen containing the Natrecor name were false and misleading because they omitted important risk information and did not qualify as "reminder labeling" (which is exempt from the risk-disclosure requirement). WLF's letter to DDMAC alleged that DDMAC's action was inappropriate, because DDMAC failed to demonstrate that Scios had actually communicated any specific uses for Natrecor.

WLF's letter was 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 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 Scios violated federal drug laws because its promotional material for Natrecor, a drug approved by FDA for treating congestive heart failure, included a picture of a seriously ill hospital patient partially submerged in water. DDMAC alleged that the picture conveyed to readers that Natrecor was indicated for treatment of congestive heart failure and noted that any advertising that discloses a drug's approved indication does not qualify as "reminder labeling" and thus must disclose all risk information. WLF's response stated that the First Amendment requires DDMAC, before concluding that an ad conveys information about a drug's approved use, to gather *some* evidence to support that conclusion, such as consumer survey data. WLF also charged that DDMAC has failed to provide any guidance in this area.

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.