News Release

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WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTERS ON BUPROPION, SPIRIVA

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) this week called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw untitled letters sent to Sandoz, Inc. on May 25, 2006 (regarding Sandoz's allegedly improper promotion of bupropion), and to Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) on May 26, 2006 (regarding BIPI's allegedly improper promotion of Spiriva Handihaler). DDMAC alleged that a professional print advertisement for bupropion was misleading because it failed to disclose all risk information. DDMAC alleged that a promotional labeling piece for Spiriva was misleading because it stated that another inhalant (Antrovent) was being discontinued in its CFC formulation without mentioning that Antrovent continued to be available in an HFA formulation. WLF's letter to DDMAC alleged that both DDMAC letters were inappropriate because they characterized promotional materials as misleading without a sufficient empirical basis.

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 May 26 letter alleged that BIPI's failure to mention the availability of Antrovent in an HFA formulation was "material" in light of the advertisement's statement that Antrovent in an inhalation aerosol formation was being discontinued. Its May 25 letter alleged that *any* advertisement that even mentions bupropion (an antidepressant) must warn that the drug is associated with increased risk of suicidal thoughts -- even ads (as here) that are "reminder advertisements," *i.e.*, advertisements that mention a drug by name but say nothing about its approved uses. While conceding that risk information is not normally required on reminder advertisements, DDMAC argued that such information is required for certain drugs (including bupropion) that entail especially large risks and thus must include "boxed warnings" on their labeling. WLF responded that DDMAC's actions run afoul of the First Amendment. WLF charged that before government may take action with respect to an omission that allegedly renders an advertisement

misleading, it must develop data demonstrating that the omission has, in fact, made the advertisement misleading. WLF charged that DDMAC sent its letters without even alleging that anyone was misled; rather, DDMAC is simply fearful that someone *might* be misled. The First Amendment does not permit censorship based solely on such unsubstantiated fears, WLF charged.

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.