News Release

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WLF CALLS ON DDMAC TO WITHDRAW UNTITLED LETTERS ON NASONEX, FLONASE

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) yesterday called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw untitled letters sent on May 7 to Schering Corp. (regarding Schering's allegedly improper promotion of Nasonex) and to GlaxoSmithKline (regarding GSK's allegedly improper promotion of Flonase). DDMAC alleged that professional detail aids for those products were false and misleading because they made unsubstantiated superiority claims as well as claims that the products are more effective than has been demonstrated by substantial evidence. WLF's letter to DDMAC alleged that both DDMAC letters were inappropriate, because they characterized promotional materials as misleading without a sufficient empirical basis and inappropriately faulted references to legitimate scientific studies.

WLF's letters were sent in connection with WLF's "DDMAC Watch" program, which is approaching its second 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 letters alleged that the detail aids stated that the products were effective in treating nasal congestion, even though Nasonex and Flonase are only approved for treating the symptoms of allergies without mentioning "congestion" in particular. WLF responded that it is impossible to read the detail aids as making unqualified efficacy claims in treating "congestion," which is, after all, a symptom and not a distinct disease state. WLF noted that both detail aids make abundantly clear that the products are to be used in treating "allergies," and the complete FDA-approved labeling information was attached to each detail aid.

The DDMAC letters also alleged that the superiority claims were misleading because they were based on studies that did not meet FDA's definition of "well-controlled studies" -- i.e., studies that form the basis for initial product approval. WLF responded that DDMAC violates the First Amendment where, as here, it seeks to prohibit a manufacturer from saying anything about the results of product comparison studies --

particularly without first considering whether any tendency to mislead could be dissipated by affixing disclaimers to the superiority claims.

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.