Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

FOR IMMEDIATE RELEASE **November 15, 2006**

WLF CALLS ON DDMAC TO WITHDRAW WARNING LETTERS ON MAXAIR, NEVANAC

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) today called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw warning letter sent to 3M Pharmaceuticals on October 19 (regarding 3M's allegedly improper promotion of Maxair Autohaler) and to Alcon Research Ltd. on October 20 (regarding Alcon's allegedly improper promotion of Nevanac. DDMAC alleged a "flashcard" for Maxair and a professional sales aid for Nevanac were false and misleading because they failed to disclose all risk information and made unsubstantiated superiority claims. WLF's letter to DDMAC alleged that both of DDMAC's letters were inappropriate, because they characterized promotional materials as misleading without a sufficient empirical basis and inappropriately devalued animal studies.

WLF's letters were 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 October 19 letter alleged that 3M's flashcard improperly claimed that Maxair, which is approved for prevention and reversal of bronchospasm, was superior to competing products. WLF responded that DDMAC lacked any empirical basis for asserting that readers of the flashcard would think that 3M was claiming superiority, and that nothing in the flashcard's language or format readily indicates that 3M was making such a claim. WLF also responded that DDMAC acted improperly in faulting 3M for citing a study that supported 3M's "easier to use" claim.

DDMAC's October 20 letter alleged that Alcon's professional sales aid improperly claimed that Nevanac, which is approved for treatment of pain associated with cataract surgery, was superior to other products and was safe even in amounts in excess of the recommended doses. WLF again responded that DDMAC lacked any empirical basis for asserting that readers would think that Alcon was claiming superiority. WLF also charged that DDMAC violates the First Amendment when, as here, it seeks to prohibit a manufacturer from saying anything about the results of studies simply because the studies

were performed on animals -- a fact Alcon fully disclosed in its sales aid. WLF noted that the studies' findings were truthful and relevant, and thus that Alcon has a First Amendment right to report the findings when (as here) it included adequate disclaimers that pointed out potential shortcomings in the studies.

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.