Washington Legal Foundation
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FOR IMMEDIATE RELEASE **March 19, 2007**

WLF CALLS ON DDMAC TO WITHDRAW LETTERS ON ROZEREM AND PROVIGIL

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) this week called on DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") to withdraw an untitled letter sent to Takeda Pharmaceuticals North America, Inc. on March 5, 2007 (regarding Takeda's allegedly improper promotion of Rozerem) and a warning letter sent to Cephalon, Inc. on February 27, 2007 (regarding Cephalon's allegedly improper promotion of Provigil). DDMAC alleged a direct-to-consumer TV advertisement for Rozerem and a presentation for Provigil (handed out to Maryland health officials) were false and misleading because they failed to disclose all risk information and (in the case of Provigil) discussed off-label uses of the drug. WLF's letter to DDMAC alleged that both of DDMAC's letters were inappropriate; WLF charged that the Rozerem letter failed to demonstrate that the TV ad was anything other than a "reminder" ad (for which no risk information is required), and that DDMAC efforts to regulate what manufacturers say to state health officials raise serious First Amendment concerns.

WLF's letters were 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 March 5 letter alleged that Takeda's TV ad did not qualify as a "reminder" advertisement because it could be understood as recommending pediatric use of Rozerem, which is approved for treatment of insomnia. WLF responded that the ad never made that claim and that DDMAC lacked any empirical basis for asserting that readers of the ad would think that Takeda was encouraging use by children simply because it showed a mother with school-age children.

DDMAC's February 27 letter faulted Cephalon for its presentation to Maryland health care officials regarding Provigil, a drug approved by FDA for improving wakefulness. WLF responded that the truthful information that Cephalon supplied regarding off-label uses of Provigil is constitutionally protected noncommercial speech; WLF noted that Cephalon was not attempting to sell any product to the Maryland

officials and thus there can be little justification for FDA regulation of manufacturer speech in that context.

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.
Copies of WLF's letters will soon be posted on its web site, www.wlf.org.