News Release

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FOR IMMEDIATE RELEASE **April 7, 2006**

WLF CALLS ON OCBQ TO WITHDRAW WARNING LETTER ON ANTHRAX VACCINE

("DDMAC Watch" Program)

The Washington Legal Foundation (WLF) today called on OCBQ (FDA's Office of Compliance and Biologics Quality) to withdraw a warning letter sent to VaxGen Inc. on March 24, 2006 regarding VaxGen's allegedly improper promotion of its anthrax vaccine rPA102. WLF's letter to OCBQ alleged that OCBQ lacks any basis for its allegation that VaxGen's activities were promotional or that VaxGen said anything that the government itself has not already said.

WLF's letter was sent in connection with WLF's recently inaugurated "DDMAC Watch" program. DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") regulates promotion of drugs; OCBQ does the same for biologics. WLF has determined that DDMAC and OCBQ have 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 or OCBQ sends a letter to a regulated company employing theories that are legally deficient or ill-advised, WLF sends a letter of our own back to DDMAC/OCBQ identifying the specific ways in which this is so.

OCBQ's letter alleged that VaxGen acted improperly by distributing at the 4th Annual Federal Biodefense Research meeting a "Question and Answer document" regarding rPA102, an investigational anthrax vaccine being developed by VaxGen. WLF's response argued that the context of VaxGen's distribution of the document makes clear that VaxGen was not trying to sell the vaccine to anyone, and therefore its truthful statements regarding rPA102 are fully protected by the First Amendment. WLF took particular issue with OCBQ's letter because the statements to which OCBQ objected were virtually identical to statements HHS made in a 2004 press release while hailing the promise of the rPA102 vaccine.

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.