News Release

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FOR IMMEDIATE RELEASE **June 14, 2007**

WLF CRITICIZES CMS EFFORTS TO DENY COVERAGE OF FDA-APPROVED DRUGS

The Washington Legal Foundation (WLF) yesterday called on the Centers for Medicare and Medicaid Services (CMS) to withdraw a proposed coverage decision memorandum that seeks to withdraw Medicare and Medicaid coverage for numerous uses of a class of biologics known as erythropoiesis stimulating agents (ESAs). In formal comments filed with the agency, WLF argued that CMS's proposed coverage decision violates CMS's statutory mandate and the Administrative Procedure Act, is unprecedented, and represents poor health care policy.

ESAs are used in treating cancer patients, particularly those undergoing chemotherapy, as well as some non-cancer patients, such as those suffering from some forms of AIDS. After extensive testing, the Food and Drug Administration (FDA) has determined that ESAs are safe and effective for a wide variety of uses. FDA has required ESAs to be labeled with "black box" warnings that remind doctors of certain health concerns associated with their use. CMS has undertaken its own benefit-risk analysis, and on the basis of that analysis has determined that it will not provide coverage for many of the uses of ESAs approved by FDA.

"CMS's proposed action is unprecedented and extremely troublesome," said WLF Chief Counsel Richard Samp after submitting WLF's comments. "Never before has the federal government threatened to deny coverage for FDA-approved uses of a drug or biologic, uses that are recommended by the patient's treating physician. It makes no sense to allow CMS or any other federal agency to second-guess the considered judgment of FDA and the treating physician that a drug or biologic is safe and effective for the use for which it has been prescribed," Samp said.

ESAs are most often prescribed for cancer patients suffering from anemia. Emerging safety concerns regarding ESAs (including thrombosis, cardiovascular events, and tumor progression) have caused FDA to mandate that more prominent safety warnings be added to the product labeling. Nonetheless, FDA has stood by its determination that for many patients the benefits of ESAs outweigh the risks. CMS is essentially overruling that determination by refusing to provide Medicare/Medicaid coverage for some of those patients.

In its submission to CMS, WLF charged that CMS's proposal no longer to cover ESA treatment for 13 separate disease indications violates the Social Security Act. WLF

argued that § 1832 of the Act, 42 U.S.C. § 1395k(a)(1), requires CMS to provide coverage for any on-label use of an FDA-approved drug or biologic. WLF argued that CMS's discretion to deny coverage is limited to occasions on which the treating physician prescribes an off-label use of an FDA-approved product.

WLF also argued that CMS's proposed action would constitute "arbitrary and capricious" decisionmaking in violation of the APA because it would place the U.S. Department of Health and Human Services (which overseas both FDA and CMS) in the position of having adopted conflicting conclusions regarding the benefit-risk profile of ESAs.

WLF also argued that CMS's proposed action would be bad for public health. WLF argued that the regulatory uncertainty created by conflicting decisions from two agencies within HHS would discourage funding for pharmaceutical research and development. WLF also cautioned that CMS's assertion of authority in this area undermines FDA's position that federal law preempts state-law failure-to-warn lawsuits -- where the suits are based on claims that a drug manufacturer should have provided warnings beyond those mandated by FDA for the product labeling.

WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government. WLF often advocates before CMS FDA and litigates against them in support of the needs of sick Americans, including winning a landmark case in May 2006 that established a constitutional right for terminally ill patients to gain access to investigational medications when no other treatment options are available.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302.
Copies of WLF comments are posted on its web site, www.wlf.org.