

**FOR IMMEDIATE RELEASE****March 21, 2005**

DEA URGED NOT TO CREATE REDUNDANT LAYER OF DRUG APPROVAL

(In re Procurement Quotas For Pain Medications)

The Washington Legal Foundation (WLF) today filed comments with the Drug Enforcement Administration (DEA) of the U.S. Department of Justice advising the agency to implement a new appropriations rider in a manner that would not create a process duplicating the FDA's drug approval process.

DEA is responsible for establishing annual procurement quotas for makers of pain medicines that are based on controlled substances (such as opioids). These quotas define the amount of the controlled substance that the company can buy for its production. In the omnibus appropriations legislation enacted on December 8, 2004, Congress included a rider forbidding the agency to establish a procurement quota for a newly-approved drug until the agency has "reviewed and provided public comments on labeling, promotion, risk management plans, and any other documents."

Public statements from DEA have given rise to concerns that the agency may intend to elevate the advisory role created by this rider into a regulatory role. By withholding review and comments, the DEA would effectively override the FDA's approval of a new pain medicine. In its comments, WLF argued that any such action would intrude on Congress's long-standing delegation of drug approval decisions to the FDA and would risk delaying the availability of pain medicines to terminally ill patients and chronic pain patients. WLF also referred the agency to a recent WLF LEGAL BACKGROUNDER on the issue by James R. Phelps and John A. Gilbert, Jr., entitled *DEA's Review of Drug Approvals Could Limit Access to Vital Medicines*.

WLF is a public interest law and policy center with supporters nationwide. WLF has frequently advocated for the interests of sick Americans in the health care system through litigation, policy papers, and media outreach. WLF has published *Conversations with ... The Honorable Dick Thornburgh and The Honorable Rudolph W. Giuliani*, a discussion between former Attorney General Dick Thornburgh and former Mayor Giuliani regarding prescription drug regulatory issues, the nature of the prescription drug abuse problem, and strategies for addressing this problem.

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For further information, contact WLF Senior Vice President for Legal Affairs David Price, (202) 588-0302. A copy of WLF's comments is posted on its web site, www.wlf.org.