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REPORT CONCLUDES THAT REGULATION OF DRUG PROMOTION VIOLATES FIRST AMENDMENT AND FEDERAL LAW

A comprehensive report issued today by the Washington Legal Foundation (WLF) concludes that Food and Drug Administration regulation of prescription drug promotion is being conducted in a manner that routinely violates both the First Amendment and FDA's statutory mandate.

The report is based on WLF's study of all regulatory compliance letters sent by FDA within the past year to pharmaceutical manufacturers. The report concludes that FDA routinely orders suppression of truthful speech, demands that manufacturers engage in "corrective advertising" in the absence of any evidence that consumers have been misled by supposedly misleading advertising, and violates federal administrative law by using compliance letters (rather than established notice-and-comment procedures) to adopt new agency policies regarding product promotion.

WLF has submitted its report to FDA in the form of a Citizen Petition. The Petition requests that Acting FDA Commissioner Andrew C. von Eschenbach direct the offices responsible for monitoring drug promotion to undertake a review of their policies and practices and to bring themselves into compliance with the First Amendment. WLF attorneys stated that WLF is contemplating litigation if FDA fails to take immediate steps to bring itself into compliance.

The FDA offices in question are the Division of Drug Marketing, Advertising, and Communications (DDMAC), which reviews promotional activities for prescription drugs, and the Office of Compliance and Biologics Quality (OCBQ), which reviews promotional activities for biological products. WLF began its monitoring of DDMAC's and OCBQ's regulatory activities in June 2005, as part of its "DDMAC Watch" project. Today's report covers the first 12 months of WLF's monitoring. During that period, WLF wrote 27 times to DDMAC and OCBQ, responding to "warning" letters and untitled letters sent by those offices to drug manufacturers; WLF's correspondence explained various reasons why the letters were legally deficient and/or ill-advised. DDMAC has never responded to any of WLF's letters.

Today's report determined that the DDMAC and OCBQ letters evidence several firmly established agency policies that have never been articulated by FDA by means of formal regulations or guidance documents. The report concludes that at least three of these policies are illegal and serve no valid health-related purpose:

- FDA policy prevents manufacturers from making product claims based on studies that do not meet FDA's narrow definition of a well-controlled study; for example, FDA only accepts double-blind studies, not open studies. FDA's policy applies regardless that FDA has no reason to doubt the truthfulness of the study, regardless whether the study has been peer-reviewed, and regardless whether the manufacturer attaches disclaimers that note any potential deficiencies in the study methodology;
- FDA policy irrationally requires disclosure of risk information twice in the same advertisement, misleading consumers and health care practitioners into believing that products are riskier than they actually are; and
- When FDA issues a "warning" letter, its policy is to compel manufacturers to engage in "corrective advertising," regardless whether FDA has evidence that any consumers have actually been misled by the allegedly misleading advertising.

The report noted that none of these policies has been articulated in any formal FDA policy document. The report concluded that FDA's use of "warning" and untitled letters to articulate new agency policy violates 21 U.S.C. § 371(h) (which requires an opportunity for public comment before FDA establishes a new interpretation of a statute or regulation) and an FDA regulation -- 21 C.F.R. § 10.115(e) (which bars the agency from resorting to informal communications to signal new or different regulatory expectations).

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 40-page report is posted on its web site, www.wlf.org. On request, WLF will make available to members of the press one or more physicians who agree with WLF's view that FDA suppression of truthful information is harming public health.