News Release

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WLF LAUNCHES "FDA/DDMAC WATCH"

WLF Launches New Program To Scrutinize FDA Advertising Regulation

The Washington Legal Foundation (WLF) today announced a new program to monitor federal regulation of prescription drug advertising. WLF has determined that the Food and Drug Administration (FDA), acting through its Division of Drug Marketing, Advertising, and Communications (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 program (to be known as "DDMAC Watch"), when DDMAC sends a letter to a drug company employing theories that are legally deficient or ill-advised, WLF will send a letter of our own back to DDMAC identifying the specific ways in which this is so. Our letter will also be publicly available. In addition to this rapid response component, WLF will analyze DDMAC warning and untitled letters to detect patterns in its oversight of drug promotion that raise legal or other issues. These analyses will also be made publicly available on a periodic basis. WLF inaugurated its program today by formally requesting DDMAC to withdraw a letter it sent to Eli Lilly and Co. regarding promotion of one of Lilly's drugs.

"Consumers are active partners in their own health care, and the pace of medical progress is rapid and hastening. The public must have access to the latest information on advances in patient care. Pharmaceutical companies are at the leading edge of medical advances, and are ideally situated to disseminate high-quality scientific information to the patients and prescribers who need it," said WLF Chief Counsel Richard Samp. "DDMAC should start providing concrete guidance to industry to help them fulfill this objective and stop playing 'gotcha' with drug companies," Samp said.

In support of its claim that DDMAC acts outside its legal authority, WLF pointed to the lack of any statutory basis for the warning and untitled letters that DDMAC routinely sends to drug companies alleging legal violations. Warning and untitled letters were invented by FDA in the 1970s as a way of acting against a company without having to go to court. With no judicial safeguards to protect against abuses, FDA often uses warning and untitled letters to allege legal theories that are unsupported by the law and demand remedial actions that it lacks legal authority to require. DDMAC is among the worst offenders, showing continued disregard for the First Amendment by alleging that materials are misleading with no evidence of how consumers understand them, requiring greater disclosure of risk information in ads than the law requires, and "requesting" corrective advertising in every warning letter even though this is not available under the law.

WLF's first action under this new program is a June 21, 2005 letter to DDMAC requesting retraction of an "untitled" letter issued to Eli Lilly and Company alleging that a direct-to-consumer (DTC) television advertisement for the company's attention-deficit disorder drug Strattera violates federal law. WLF objected to DDMAC's failure to provide any evidence supporting its contention that the advertisement is misleading to consumers, and reminded DDMAC that its actions must be consistent with the First Amendment and fulfill applicable procedural requirements.

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 June 21, 2005 letter to FDA is posted on its web site, www.wlf.org.