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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 a one-year period 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.

The report was issued in connection with WLF's "DDMAC Watch" program, which has now been in existence for two-and-one-half years. WLF has determined that DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") 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 DDMAC Watch program, when DDMAC sends a letter to a drug company employing theories that are legally deficient or ill-advised, WLF sends a letter of our own back to DDMAC identifying the specific ways in which this is so.

Today's report covers the second 12 months of WLF's monitoring. WLF issued a similar report following the first year of the DDMAC Watch program. To date, WLF has written responses to 53 DDMAC letters sent to pharmaceutical companies regarding their promotional practices.

Today's report determined that the DDMAC 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 a number of these policies are illegal and serve no valid health-related purpose:

- FDA has an established policy of allowing drug manufacturers to make promotional claims only if those claims are supported by "substantial evidence" – an extremely high standard that requires evidence equivalent, in terms of type and quantity, to the evidence required for new drug approval. DDMAC completely bans statements that do not meet this "gold standard," regardless whether the

statements are truthful and non-misleading and are based on elaborate clinical studies. Such a strict standard does not comply with the First Amendment.

- FDA has an established policy of determining that a promotional piece is misleading based solely on the understanding of DDMAC enforcement personnel; DDMAC makes no effort, before making a finding that a piece is misleading, to determine whether any consumers were actually misled by the piece. Rather, DDMAC brings a we-know-it-when-we-see-it approach to regulation – an approach incompatible with the First Amendment.
- 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. Corrective advertising is a radical measure whose constitutionality is subject to question, because it effectively compels a private party to make statements to the public with which it might disagree.
- 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
- FDA has a policy of using warning and untitled letters to establish policy. That policy is inconsistent with federal law and FDA regulations, which require the agency to provide notice and an opportunity for comment from interested parties before the agency announces new 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 27-page report is posted on its web site, www.wlf.org.