News Release

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WLF TESTIFIES BEFORE FDA IN SUPPORT OF BROADENING ADVERTISING RIGHTS

A Washington Legal Foundation (WLF) attorney testified today before a Food and Drug Administration (FDA) panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer (DTC) advertising.

Speaking before a panel created for the purpose of looking into possible changes in DTC advertising guidelines, WLF Chief Counsel Richard Samp asserted that FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) needs to rein in its efforts to suppress advertising, and step in only when advertisements are likely to mislead consumers.

When FDA announced that it would be holding hearings on November 1 and 2, its announcement suggested that FDA is considering moving in the other direction and imposing additional restrictions on advertising. Many hearing witnesses called for severely limiting drug ads, calling them inherently biased and misleading. WLF's Samp countered that DTC advertising has played a vital public health role in recent years by increasing consumer awareness of treatment options.

Among those who testified in favor of increased restrictions on advertising were representatives of Public Citizen, Commercial Alert, Prescription Access Litigation, the National Research Center for Women & Families, Drugawareness.org, Consumers Union, and the AARP. Others among the 38 witnesses included representatives from the American Medical Association, the Pharmaceutical Research and Manufacturers of American, and Pfizer.

In his testimony, Samp described WLF's recently inaugurated "DDMAC Watch" program. WLF has determined that 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. Samp explained that 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. Samp testified that despite DDMAC's failure to date to respond to the letters, WLF intends to press on and may resort to litigation if DDMAC persists in its practices.

Samp was particularly critical of DDMAC's efforts to prohibit manufacturer dissemination of scientifically valid clinical study reports to health care practitioners and

patients. DDMAC routinely demands that such studies not be disseminated if they do not meet FDA's super-strict definition of a well-controlled study, even though the studies usually are peer-reviewed and often contain information that could be extremely valuable to doctors and their patients. Samp argued that if DDMAC has concerns about the design of a study, it should require the manufacturer to include disclaimers that point out potential study deficiencies (*e.g.*, many studies are less reliable because they are "open" studies in which patients know what drugs they are receiving) rather than prohibiting *all* discussion of the study.

Samp also called on DDMAC to commit all its advertising rules to writing, either in the form of regulations or guidance documents. Samp said that manufacturers need better guidelines regarding what advertising DDMAC deems acceptable. Samp said that manufacturers often discover that DDMAC disapproves of particular advertising practices only after they receive a Warning Letter from FDA, demanding that the company cease its advertising and engage in "corrective advertising."

WLF is a public interest law and policy center with supporters in all 50 States. WLF devotes a significant portion of its resources to opposing unwarranted government restrictions on commercial speech, particularly speech related to pharmaceutical products.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of Mr. Samp's testimony is posted on WLF's web site, www.wlf.org.