Press Release

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WLF Warns FDA: Adopting Revised Reprint Guidance Could Place Agency in Contempt of Court

(In re: Revised Draft Guidance on Distributing Publications on Off-Label Uses)

"The Draft Guidance appears to violate terms of a permanent injunction WLF obtained against FDA in 1998 … and raises serious First Amendment concerns …By attempting to restrict truthful speech, FDA is endangering public health."
—Rich Samp, WLF Chief Counsel

WASHINGTON, DC—The Washington Legal Foundation yesterday warned the Food and Drug Administration that the agency would violate terms of a federal court injunction were it to adopt its revised draft guidance on reprint practices for articles/medical texts that contain off-label information concerning FDA-approved products. In formal comments filed in response to the Draft Guidance, WLF reminded FDA that a federal court injunction (issued in 1998 in *Washington Legal Found. v. Friedman*) prohibits the agency from preventing manufacturers from disseminating peer-reviewed medical journal articles and medical texts that contain truthful off-label information. It asserted that FDA officials could be held in contempt of court if they attempt to enforce speech restrictions outlined in the Draft Guidance that violate the injunction.

WLF argued that the Draft Guidance will violate both the injunction and the First Amendment unless it substantially broadens the type of studies it deems acceptable subjects for distributed articles. The Draft Guidance would limit distribution to materials that report on "adequate and well-controlled clinical investigations," a standard that would virtually eliminate dissemination. WLF also pointed out that the Draft Guidance imposes so many burdens on those seeking to disseminate articles and texts (*e.g.*, they must distribute extensive bibliographies) that it would dissuade many manufacturers from speaking because compliance would be far too onerous.

FDA has long recognized that off-label treatments play a vital role in medical care. WLF noted that patients will not receive state-of-the-art, off-label therapies if their doctors are not informed about those therapies. It argued that manufacturers—who possess both the resources and the incentives necessary to exert the effort—have traditionally played a large and beneficial role in supporting the dissemination of information about cutting-edge uses of FDA-approved products.

Upon filing its comments, WLF issued the following statement by Chief Counsel Richard Samp: "The Draft Guidance appears to violate terms of a permanent injunction WLF obtained against FDA in 1998 from the US District Court for the District of Columbia. Moreover, it raises serious First Amendment concerns regarding manufacturers' rights to speak truthfully about important health care issues. By attempting to restrict truthful speech, FDA is endangering public health."

WLF is a public interest law firm and policy center that regularly litigates in support of the free speech rights of the business community.

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