

# News Release

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## **FDA URGED TO COMPLY WITH FIRST AMENDMENT LIMITATIONS ON ITS REGULATORY AUTHORITY**

The Washington Legal Foundation (WLF) this week urged the Food and Drug Administration (FDA) to modify its regulatory activities so that they no longer violate the First Amendment rights of those seeking to speak truthfully about pharmaceutical products. WLF argued that recent court decisions make clear that FDA is subject to First Amendment constraints and that much of its regulatory activity does not conform to those constraints.

WLF made its submission to FDA in response to FDA's May 16 request for comments on First Amendment issues. That request apparently was prompted by the U.S. Supreme Court's recent decision in *Thompson v. Western States Medical Center*, in which the Court ruled for the first time that FDA regulation is subject to First Amendment constraints.

WLF's submission focused primarily on FDA efforts to suppress dissemination of information about off-label uses of FDA-approved products. WLF argued that the First Amendment prohibits such FDA suppression efforts when aimed at truthful information in the form of peer-reviewed journal articles or medical texts, or when presented in conjunction with an accredited scientific symposium. WLF also argued that allowing the free flow of such truthful information provides significant benefits in the form of improved public health.

WLF takes great pride in the mere fact that FDA is requesting public input on First Amendment issues. For more than a decade, WLF has worked actively to reduce FDA restrictions on truthful speech and has repeatedly pointed out the need for FDA to begin complying with First Amendment rules. When WLF first began raising the issue, FDA took the position that it was largely exempt from First Amendment restraints. WLF's efforts have played a key role in changing the agency's viewpoint.

WLF battled FDA in court throughout the 1990's on the issue of off-label speech. Those battles paid off, when a federal court in the District of Columbia ruled in 1998 in *WLF v. Henney* that many of FDA's off-label speech restrictions violated the First Amendment. The injunction

issued by the court against FDA in that case is still in effect. But WLF is still battling with the agency regarding how far FDA needs to go to comply with the court ruling.

WLF also has played a key role in easing FDA restrictions on direct-to-consumer advertising of prescription drugs and medical devices, and advertising by pharmacies regarding their drug compounding activities; and FDA restrictions on manufacturer websites. A Citizen Petition filed by WLF with FDA on direct-to-consumer advertising led to FDA public hearings on the issue, at which WLF testified. Following those hearings, FDA eased considerably its restrictions on broadcast advertising; WLF continues to work for a similar relaxation of rules regarding print advertising. WLF's Citizen Petition on pharmacy compounding heightened public awareness of First Amendment issues surrounding FDA regulation in that area and led ultimately to the Supreme Court's pathbreaking First Amendment decision in *Thompson v. Western States Medical Center*. A WLF Citizen Petition concerning FDA restrictions on what manufacturers could say on their websites led the agency to back off some of its more extreme enforcement actions in that area.

The overwhelming majority of those submitting comments to FDA urged the agency to increase its recognition of First Amendment rights. Several commenters, however, asserted that FDA should be increasing its regulation manufacturer's speech. WLF intends to take advantage of FDA's offer to accept an additional round of comments, by filing a brief responding to those who see a need for additional FDA speech regulation.

WLF is a public interest law and policy center with supporters in all 50 States. WLF devotes a significant portion of its resources to defending the rights of individuals and businesses faced with excessive government regulation.

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