

INVESTIGATIONS OF DRUG PROMOTION THREATEN FIRST AMENDMENT RIGHTS

by
Richard A. Samp

Federal regulators cannot seem to agree on whether more truthful information about health care options is good or bad for consumers. On the one hand, the Food and Drug Administration (FDA) recently liberalized drug advertising rules to allow pharmaceutical companies greater leeway in conveying useful information in print advertising. Former FDA Commissioner Mark McClellan has encouraged increased emphasis on health information in food labels and ads. Now that he heads HHS's Centers for Medicare & Medicaid Services, McClellan has called for increased study on the risks and benefits of off-label prescription drug use — information that can only benefit consumers.

But while McClellan has championed the empowerment of consumers by providing them with more truthful healthcare information, others in the federal government have been working diligently to suppress that same information. Major drug companies with increasing frequency have become the targets of criminal probes and tort suits for doing the very things that McClellan has encouraged: providing truthful information about their products. Federal prosecutors in Boston and Philadelphia are premising their investigations in substantial part on their assertion that it is a criminal offense for a company to disseminate information about off-label product uses. Within the past month, for example, Eli Lilly & Co. announced that it was being criminally investigated for its promotion of the anti-depressant Prozac. Press reports indicate that Pfizer, Inc. is on the verge of paying hundreds of millions of dollars to settle a False Claims Act suit alleging off-label promotion of Neurontin. Pfizer may have felt itself backed into a corner by a bizarre trial court ruling that truth is no defense in a False Claims Act suit. HHS's Office of Inspector General has also weighed in against truthful speech, even suggesting that the provision of information to doctors may in some instances violate the federal anti-kickback statute.

What makes the speech-suppression activities of some federal officials all the more amazing is that the federal courts have already ruled that such activities violate the First Amendment. In *Washington Legal Found. v. Friedman*, the federal district court in Washington held that truthful speech about off-label use of FDA-approved products is in many instances protected by the First Amendment. The court held that the federal government is barred by the First Amendment from attempting to interfere with such drug company activities as distributing peer-reviewed medical journal articles that discuss off-label uses of the company's products, or providing financial support for continuing medical education seminars at which off-label uses of their products are being discussed.

Apparently, not all arms of the federal government have heard the word; some of the ongoing criminal investigations purportedly focus on the very types of promotional activities held to be

protected in *Friedman*. Drug companies are reluctant to fight too hard in support of speech rights; public hostility to prosecutors might be viewed as grounds for barring their participation in federal programs. But WLF is doing all it can to make sure that federal officials get the word; it has written to senior officials at the Justice Department and HHS to demand that such officials at all levels begin respecting the First Amendment. WLF urges others concerned about health care and free speech to do the same.

Richard A. Samp is Chief Counsel to the Washington Legal Foundation.

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