

PRESS RELEASE

First Amendment Analysis of Proposed Restrictions on Prescription Drug Advertising Reveals Flaws in Congressional Proposals to Curtail the Speech

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Washington, DC—The current debate on Capitol Hill over rising health care costs has prompted some to try to link the issue to prescription drug advertising—and to propose using the tax laws or other measures to effectively suppress the ads by imposing discriminatory burdens on the advertisers. A new legal analysis by WRF attorneys Bert W. Rein, John F. Kamp and Rosemary C. Harold demonstrates that such proposals raise serious First Amendment concerns. The Washington Legal Foundation has just published “Proposed Limits on Prescription Drug Ads: A Constitutional Analysis,” as part of WLF’s Working Papers series of legal commentaries.

“The latest proposals to restrict prescription drug ads would face First Amendment scrutiny even though they do not explicitly call for banning the advertising,” said Bert Rein, a name partner in the firm and an expert on the intersection of food and drug law and free speech. “If that point were ever in doubt, however, it has been laid to rest by the Supreme Court’s recent decision in *Thompson v. Western States Medical Center*.” In April 2002, the Court struck down a prohibition imposed by the Food and Drug Administration (“FDA”) on advertisements about so-called “compounded” drugs, which are custom-mixed by a pharmacist pursuant to a doctor’s directives.

Arguments about ads promoting manufacturer-made prescription drugs—also known as “direct-to-consumer” (“DTC”) advertisements—have been percolating in policy circles for several years. Critics have denounced the messages as unseemly, potentially misleading or

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otherwise wasteful in some fashion. Yet as WRF's analysis notes, recent studies conducted by the U.S. Food and Drug Administration ("FDA") show that consumers find DTC advertising helpful in learning more about medical conditions that may affect them. Even former FDA Commissioner David Kessler, who once fiercely opposed DTC ads, recently conceded that they provide "a lot of educational benefit." Consequently, efforts to restrict the advertising implicates not only the First Amendment rights of pharmaceutical manufacturers to speak but also the First Amendment rights of consumers to learn more about these potential treatment options.

The most actively debated legislative proposals would employ a sophisticated approach for effectively suppressing DTC ads: establishing a taxing or benefit scheme that would penalize pharmaceutical manufacturers who engage in the advertising. The WRF analysis demonstrates that this sort of indirect burden on speech would not escape court review. Indeed, *Western States* itself involved a type of indirect ban. The challenged restriction there did not bar pharmacists from advertising the names of the drugs they compounded—but if they did so, they could face civil or criminal penalties for evading drug approval processes normally not applied to compounded prescriptions. The indirectness of this scheme did not stop the Supreme Court from striking it down. WRF's analysis explains that *Western States* is simply the latest case in which the Court recognized that the First Amendment "nullifies sophisticated as well as simple-minded modes" of infringing on speech rights. The precedent includes decisions overturning speech-based distinctions that limit eligibility for government benefits, particularly when the facts suggest that there is some flavor of government coercion with respect to the messages being suppressed.

The WRF analysis also notes that proponents of the DTC restraints can not assume that their proposals will skirt the highest level of First Amendment review. Some types of DTC messages—such as the so-called "help-seeking" ads—simply inform consumers about health conditions and urge them to consult their doctors to discuss therapeutic options, without naming any particular drug. These messages do not "propose a commercial transaction" in the manner of traditional advertising. Rather, they simply convey scientific and health information and so may well qualify for full First Amendment protection.

Even under the lesser constitutional protection accorded to commercial speech, however, the current legislative proposals to suppress DTC advertising would face substantial legal hurdles. The WRF analysis demonstrates that these measures are likely to fail under several prongs of *Central Hudson* analysis applied to commercial speech restrictions:

- **Speech not false or misleading:** Although the government may act against false or misleading commercial speech, DTC advertising clearly is neither—because the government, through the FDA, already has acted to ensure that prescription drugs are safe and effective and that the ads provide "fair balance" by disclosing possible risks and side effects.
- **Government goal not "directly advanced" by restrictions:** If consumer safety is not really the issue, presumably the supporters of a discriminatory taxing or benefits scheme hope to limit the costs of a new prescription drug benefit program. But it is not clear that the proposed restrictions would serve that purpose because the available economic data does not conclusively link the ads to the price of an individual prescription. There is some evidence to suggest a connection between the ads and the

aggregate demand for drugs—presumably because more people are learning about drug therapies that may help them, consulting their physicians and obtaining appropriate prescriptions. Any cost savings to the government, therefore, might come only by keeping some consumers ignorant about their health-care options.

- Restrictions more extensive than necessary: Proponents of the current proposals to suppress DTC advertising would have a difficult time showing that they could not achieve their fiscal goals by measures that do not infringe on speech. Alternatives would include capping government-supported benefits at a certain level or limiting the benefit to treatment of certain types of health conditions. In addition, supporters of the restrictions also would have to grapple with the constitutional difficulties of suppressing one source of information about prescription drugs—knowledgeable manufacturers—while allowing other sources, such as unregulated Internet speakers, free rein to say almost anything about the same products.

To download the entire 40-page WRF analysis [click here](#). The paper and a two-page executive summary are also available from the Washington Legal Foundation (202.588.0302).