

April 27, 2007



UNIVERSITY OF RICHMOND
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The Honorable Harry Reid
The Honorable Mitch McConnell
United States Senate
Washington, D.C. 20510

Dear Senator Reid and Senator McConnell:

I am writing to offer my opinion regarding the constitutionality of the advertising provisions of S. 1082, the Food and Drug Administration Revitalization Act. I write in my capacity as a constitutional law scholar and litigator with special expertise in First Amendment matters.

It is my view that the advertising restrictions contained in S. 1082 would not survive a First Amendment challenge. The provisions as written improperly deny consumers direct access to truthful and accurate information about new drug treatments. The provisions are likely to tie up Food and Drug Administration (“FDA”) resources in unnecessary litigation, and are in the end not likely to withstand constitutional attack. I therefore urge you to carefully consider more narrowly tailored alternatives to the current provisions in section 202 of S. 1082, provisions that call for compulsory pre-review of prescription drug advertisements, mandate inclusion of specific language in such advertisements, and authorize the FDA to place a two-year moratorium on advertising as part of a drug’s Risk Evaluation and Mitigation Strategy (“REMS”).

The Regulation of Commercial Speech and Paternalism

Government regulation of commercial speech is subject to review under the four-part test set forth in *Central Hudson Gas and Elec. v. Public Serv. Comm’n*, 447 U.S. 557 (1980) and often applied in subsequent decisions. *See, e.g., Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002). Under that test:

- Truthful and non-misleading commercial speech is constitutionally protected;
- Regulation of such speech must advance a substantial government interest;
- Regulation must directly and materially advance the asserted government interest.
- Regulation must not be more extensive than is necessary to serve the public interest-it must be narrowly tailored and be the last, not the first, resort in advancing the government’s interest.

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The Supreme Court's commercial speech jurisprudence is founded on the First Amendment protection of the public's right to truthful and accurate information about both prescription drugs and other products that may affect the health and welfare of citizens. The Court first expressly established the applicability of the First Amendment to advertising in a case challenging a state restriction to prescription drug advertising.¹ The trajectory of those cases is unmistakable; in decision after decision the Court has advanced protection for advertising and shown a manifest hostility towards paternalistically "protecting" the public from commercial speech that is truthful and not misleading.² As the Court noted in *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996), a case that invalidated a state law prohibiting advertising for the price of liquor:

[A] State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it [B]ans against truthful, nonmisleading commercial speech ... usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. . .

The Supreme Court has also consistently held that any prior restraint of speech comes with a "heavy presumption" against its constitutional validity. The government carries a heavy burden in demonstrating the justification for imposition of such a restraint.³

¹ *Virginia St. Bd. Of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976)

² See, e.g., *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 371 (2002) (striking down restrictions on pharmaceutical advertising); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554-55 (2001) (striking down some and sustaining some restrictions on tobacco advertising); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 195-96 (1999) (striking down casino gambling advertising limitations); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497, 503 (1996) (striking down liquor advertisement restrictions); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491 (1995) (striking down beer advertising regulations); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 74-75 (1983) (concluding that a statute banning unsolicited mailings advertising contraceptives to aid parental authority over teaching their children about birth control was unconstitutional); *Central Hudson Gas and Elec. v. Public Serv. Comm'n*, 447 U.S. 557, 571-72 (striking down restrictions on advertising statements by public utilities); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-73 (1976) (striking down restrictions on pharmaceutical advertising); *Bigelow v. Virginia*, 421 U.S. 809, 829 (1975) (striking down restrictions on abortion advertising).

³ See, e.g. *Org. for a Better Austin v. Keefe*, 402 U.S. 415, 418-19 (1971).

The Proposed REMS Advertising Restrictions

S. 1082 would authorize the FDA to establish a Risk Evaluation and Mitigation Strategy as a condition of approval of each New Drug Application. The proposed statute would authorize FDA to impose, as elements of a REMS, requirements that (1) all advertising for the approved product be submitted to the FDA for review and approval prior to launch; (2) FDA-mandated safety statements be included in each advertisement; and (3) a moratorium of up to two years be placed on all advertising for a specific prescription drug.

Both the prereview and the moratorium provisions raise the specter of a prior restraint on truthful and non-misleading speech regarding products that are of great interest and concern to consumers. Further, neither provision appears to directly advance a substantial government interest. To the extent that the government's interest here may be to dampen patient interest in or utilization of new drug, the Court has previously made clear that the government may not use speech restrictions as a means to control consumption of a product.⁴ Certainly, the FDA has a vital role in minimizing the adverse events that may occur in newly-approved drugs. However, the proposed legislation requires prereview of advertising and/or allows it to be banned in its entirety prior to any showing of adverse events in the public at large.

To the extent that the government's interest in regulating information restricted in this Bill is grounded in an attempt to prevent an unknown event from occurring, courts are likely to determine that this interest is far outweighed by the harm that could occur from taking truthful and non-misleading information away from consumers. Advertising information about new prescription medications has and will continue to prompt tens of millions of Americans to ask a doctor about a medical condition, whether they ultimately receive the advertised medication or not. The doctor remains the most important safety factor that stands between a person who sees an advertisement for a prescription medication and the ability to obtain that medication. The legislation fails to account for the effect of this loss of information and offers no evidence that the ban, prereview or mandated speech will help avoid adverse events.

More Narrowly Tailored Tools Are Readily Available

Historically, where most commercial speech restrictions tend to fail is in the fourth prong of the *Central Hudson* test – which requires assessment of whether the restriction is more extensive than necessary to serve the public interest.

⁴ See, e.g., *44 Liquormart, Inc.*, 517 U.S. at 507-08 (bans on truthful and non-misleading commercial speech “not only hinder consumer choice, but also impede debate over central issues of public policy”).

Numerous tools are available to ensure that advertising for a prescription drug is truthful and nonmisleading, short of the extreme measures adopted in the Bill. Courts are likely to require the government to pursue its ends through these alternatives before approving bans on truthful information or the government's direct dictation of the content of advertising.

Numerous alternatives exist, including:

- A voluntary prereview process that allows FDA to provide "safe harbor" comments on advertising, but does not restrain dissemination of that advertising unless or until FDA's comments are communicated to the manufacturer and incorporated into the ad;
- Greater emphasis on enforcement against any false or misleading drug advertising, through civil penalty provisions for violative advertising and increased budgetary resources for enforcement.
- In keeping with the First Amendment principle emphasizing that the solution to most governmental concerns regarding speech is more speech, greater use of FDA's "bully pulpit" to provide the Agency's scientific opinions on new information regarding emerging drug risks to the public at large.

No reasonable person would dispute that the FDA has a vital role to play in ensuring that doctors and patients make the best treatment decisions possible. Restricting information on newly-approved drug treatments, however, does nothing to enhance those decisions and runs contrary to the free-market principles of the First Amendment and the economic marketplace, substituting the American faith that consumers suffer when the government paternalistically restricts the free flow of truthful information about lawful products. I would urge you to carefully consider alternatives that do not impede the free flow of truthful information about new drugs, vindicating both the public interest in sound doctor-patient health care decisions, and the free speech principles embraced in the United States Constitution.

Respectfully,



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