Legal Opinion Letter

WLF Washington Legal Foundation

Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Vol. 18 No. 10 May 9, 2008

DTC ADS PROMOTE INFORMED HEALTH CARE DECISION-MAKING

by
Richard A. Samp

Prescription drug advertising directed at consumers has grown slowly but steadily in this country over the past 25 years. That growth has accompanied the introduction of new drugs that provide significant health benefits to the American consumer; there is little doubt that advertising has played a major role in increasing public awareness of the availability of those new drugs. But increased advertising also has its critics. There have been efforts in Congress to abolish tax deductibility for direct-to-consumer ("DTC") advertising of prescription drugs; to step up enforcement efforts against allegedly deceptive advertising; and even to prohibit DTC advertising altogether for the first several years following a drug's initial approval. All such efforts are largely misguided. No one supports misleading advertising; but instances of misleading advertising have been few and far between, and the benefits of DTC advertising have vastly exceeded any perceived costs.

Undertreatment. The number one complaint of critics is that DTC advertising leads to unnecessary drug utilization and inflated health care spending. In fact, most knowledgeable health care specialists believe that those critics have the issue backwards: the real problem is that many serious medical conditions go undiagnosed and untreated. For example, a major study by RAND Health in 2003 found that Americans receive only about one-half of recommended health care; they failed to receive appropriate medications in at least 30% of all cases studied.[1] DTC advertising and other drug industry promotional activity can help to alleviate that underuse by prompting patients to talk to their doctors about medical conditions that might otherwise go untreated. Patients are doing just that: in 2006, 56 million Americans had conversations with their doctors about appropriate medications after seeing a DTC ad.[2]

Not surprisingly, expenditures on prescription drugs are rising as more patients become aware of available medications and begin using them. But increased utilization brought about by increased awareness of options is cause for celebration, not for concern. Many lives can be saved as consumers become increasingly aware of the availability of medications to treat high blood pressure. The quality of lives of millions more can be improved as consumers become aware of the availability of allergy medications that do not cause drowsiness. But while ads have increased usage, the FTC concluded in a 2003 study that there is "little, if any, evidence" that DTC ads have led to increases in drug prices.

Patient Misuse of Information. Critics often suggest that even accurate DTC advertising will be misunderstood by patients, who will then seek medications that may not be appropriate for them. The evidence does not bear out such criticism. Patients cannot, of course, gain access to prescription medications without the consent of their doctors. There is little evidence to suggest that DTC ads are causing doctors to write prescriptions they deem inappropriate but that they feel compelled to write due to patient insistence. Indeed,

[1] E.A. McGlynn, *et al.*, "The Quality of Health Care Delivered to Adults in the United States," 348 N.E. J. OF MED. 2635-45 (June 2003).

[2] Prevention Magazine, *The National Survey on Consumer Reaction to DTC Advertising of Prescription Medications* (2007).

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

surveys indicate that doctors welcome the patient inquiries prompted by DTC ads.[3] Virtually all doctors surveyed said that patients who reported seeing DTC ads did not try to influence the course of treatment in a way that would have been harmful. *Id.* Two-thirds of doctors believe that DTC advertising helps them have better discussions with their patients.[4] Also, DTC ads are not causing patients to seek higher-cost brands when lower-cost alternatives are available: more than two-thirds of all drug prescriptions in this country are for low-cost generics.[5]

Moreover, any efforts to restrict DTC ads based on concerns that patients cannot properly handle the information conveyed runs smack dab into the First Amendment. As the U.S. Supreme Court recently explained in striking down, as a violation of free speech rights, a congressional ban on advertising of drug compounding, "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Thompson v. Western States Medical Center*, 535 U.S. 357, 375 (2002).

Misleading Advertisements. DTC ads are subject to extensive FDA regulation to ensure their accuracy. Among other things, all ads must include a "brief summary" relating to side effects, contraindications, and effectiveness. 21 U.S.C. § 352(n). Failure to meet that requirement renders the advertised drug "misbranded" and subject to seizure. *Id.* As many have noted, the "brief summary" required by FDA is anything but brief; FDA requires detailed information virtually identical to the information required on approved product labeling. DDMAC (FDA's "Division of Drug Marketing, Advertising, and Communications") carefully monitors DTC advertising and comes down hard on drug manufacturers that fail to comply with advertising requirements. PhRMA, the drug industry trade group, in 2005 adopted voluntary principles regarding DTC advertising standards that go well beyond what FDA requires. DTC ads containing misleading information simply are not a common phenomenon.

Those who complain of misleading ads point to a handful of products that were advertised to consumers soon after receiving FDA approval, only to be pulled from the market after new research suggested previously unknown risks. But when the risks are just as unknown to the manufacturer as to all others, ads that did not mention the risk can hardly be called misleading. Nor is there reason to ban advertising in the period after a drug is first approved. While such a ban might have prevented harm in those few cases in which post-approval risks are uncovered, it would also delay public awareness of the vast majority of new drugs that provide substantial benefits and which prove to be just as safe as FDA initially determined them to be. Many more lives are lost due to delayed introduction of lifesaving medications than are lost due to the occasional approval of a drug later determined to raise significant safety concerns.

Moreover, the First Amendment absolutely prohibits using speech restrictions as a means of addressing this issue. The Supreme Court has made clear that "if the Government could achieve its interests in a manner that does not restrict speech, . . . the Government must do so." *Western States*, 535 U.S. at 371. In other words, the appropriate way to deal with the possibility that use of a drug presents unknown risks is to address the drug's sale, not limit the right to speak truthfully about it.

Providing adequate and affordable health care to all Americans should be among our highest priorities. DTC advertising is part of the solution, not part of the problem. Those who seek to restrict such ads can do so only by ignoring both that reality and First Amendment free speech rights.

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[3] In a 2004 FDA survey, over 90% of patients who asked about an advertised drug reported that their doctor "welcomed the question." K. Aikin, *et al.,* "Patient and Physician Attitudes and Behavior Associated with DTC Promotion of Prescription Drugs," FDA Center for Drug Evaluation and Research (Nov. 2004).

[4] J.S. Weissman, *et al.,* "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," *Health Affairs Web Exclusive* (Apr. 2004).

[5] PhRMA, *The Facts About Pharmaceutical Marketing and Promotion* at 4 (2008).

ISBN 1056 3059