

# Direct-to-Consumer Drug Marketing: Public Service or Disservice?

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## Abstract

Pharmaceutical industry spending on direct-to-consumer advertising has been increasing rapidly. While the primary goal of direct-to-consumer advertising is to sell drugs, supposed secondary goals include patient education and improved health. However, these benefits of direct-to-consumer advertising are unproved. Moreover, such advertising may create unnecessary tension between the patient and the patient's physician and insurer, and may divert physicians' efforts away from important patient concerns, and toward marketing-generated discussions. On the other hand, direct-to-consumer advertising may lead to patient-doctor encounters that would not have occurred otherwise. Direct-to-consumer advertising should be modified to unambiguously benefit the health-care interests of consumers and patients.

**Key Words:** Prescription drugs, pharmaceutical industry, marketing, advertising.

## Introduction

DIRECT-TO-CONSUMER (DTC) marketing is a growing area of pharmaceutical industry activity. Currently, such activity is of unclear net benefit to patients. Arguments supporting DTC advertising include its informational content and patient empowerment through education. However, the primary goal of DTC advertising is to sell medication. The primary motivation is financial profit. Is DTC advertising benign, helpful, or harmful to patients? To date, the effects of DTC advertising have not been studied rigorously, although some data exist. In this essay, we discuss implications of DTC advertising

and suggest alternative approaches which are more apt to support patients' interests.

## Background

The pharmaceutical industry is one of the most profitable industries on the Fortune 500 list. In this high stakes arena, a single successful drug can generate billions of dollars in revenue. Research and development for failed drugs can cost billions of dollars as well. Pressures to generate revenue have led the pharmaceutical industry to direct advertising to patients in addition to health-care professionals. For some drugs, such as Claritin<sup>®</sup> and Zyban<sup>®</sup>, 90% of promotional spending is directed toward consumers (1). While spending on advertising in medical journals is decreasing, DTC advertising spending for prescription drugs is increasing rapidly. In 1996, \$600 million was spent (2). By 1999, annual spending exceeded \$1.5 billion (1). Drug manufacturers may find that generating consumer demand is an effective supplemental strategy to alter managed care formularies, because physicians' influence and prescribing autonomy are constrained within these plans. Some managed care organizations are responding to these pharmaceutical industry initiatives by providing physicians with guidance in dealing with patient requests for non-covered proprietary drugs.

The Food and Drug Administration (FDA) has had the authority to regulate pharmaceutical advertising since Congress gave it jurisdiction in 1962. In 1983, the FDA commissioner, re-

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sponding to several DTC advertisements, requested a voluntary two-year moratorium on DTC advertising, which began in October 1983. Public pressure and drug industry initiatives forced the FDA to reexamine its long-standing policy opposing DTC advertising of prescription medications. The FDA expressed reservations about the content and priority of DTC advertising, citing an inherent conflict between promotional content and objective information (3). In 1985, the FDA permitted DTC advertising under the same standards that existed for advertising to physicians, namely, fair balance and full disclosure (4). In 1997, after years of wrestling with DTC advertising, the FDA published draft guidelines for advertising directed to consumers; these guidelines stipulated truthful description of the product's indication, and a "major statement" about the associated side effects and contraindications. However, the brief summary of the drug's indication, contraindications and side effects required for promotional advertisements may be omitted if instructions are provided for how consumers can obtain detailed information about the drug, e.g., toll-free telephone number, internet web address, referring patients to pharmacists or physicians (5). Final guidelines are under development. Unfortunately, the FDA is not empowered, and does not have the resources, to require preapproval of advertisements. These deficits compromise the FDA's effectiveness in regulating DTC activity.

The pharmaceutical industry's history of noncompliance with FDA regulation of physician and consumer advertising is well documented. Wilkes et al. studied 109 full-page advertisements appearing in ten leading medical journals, along with all available references cited in the advertisements (6). They evaluated these advertisements against FDA guidelines and concluded that guidelines for balanced presentation of material were violated in 30–40% of cases. Fifty-seven percent of advertisements were found to have little or no educational value. Rothermich et al. (7) examined 94 prescription drug advertisements in three medical journals. These investigators found that health-related quality of life claims in the advertisements were usually implied and that 40% of the advertisements did not comply with FDA regulations. The FDA's Division of Marketing, Advertising, and Communication maintains a web page listing its regulatory correspondence with drug manufacturers regarding alleged violations in advertising ([www.fda.gov/cder/ddmac](http://www.fda.gov/cder/ddmac)).

Empiric information surrounding DTC advertising is limited. A survey of family physicians found a degree of ambivalence about DTC advertising, although most physicians expressed negative views. Advantages of DTC advertising cited by these physicians included patient information and the promotion of patient-doctor communication, while disadvantages included cost and misinformation (8). Ninety-five percent of these physicians were approached by patients with requests for specific prescription medications within a six-month period of learning of them.

Other studies suggest both positive and negative effects of DTC advertising on consumers. A study of 1500 subjects exposed to magazine or television advertisements for fictitious prescription drugs found that the television advertisements were more likely than magazines to promote consultation with a physician about the particular drugs. Magazine advertisements had less of an effect on consultation-seeking behavior, but were more likely to enhance the patients' view of their authority in drug decision making (9, 10). A convenience sample of 202 outpatients was surveyed after viewing a televised advertisement. This study found that patients viewing an advertisement with both promotional and risk-related product information have difficulty in learning either type of information (11). A study of 150 television commercials for over-the-counter drugs found that consumer awareness of the product was primary, education was not well integrated into the advertisement, and a casual attitude toward drug use was encouraged (12). A survey by the American Pharmaceutical Association found that about 30% of consumers who had seen a DTC advertisement asked their physicians questions about the product and a similar proportion asked their physicians about the associated health condition (13). Of those who spoke to their physician after seeing an advertisement, about one-third asked for a prescription for the advertised medication. The survey found that consumers described the advertisements as unclear, with television advertisements less useful than print advertisements. A telephone survey of 329 randomly selected California consumers found that awareness of DTC advertisements correlated with being affected by the health condition the advertised drug was developed to treat (14). This survey also found that 50% of respondents thought advertisements had to be approved by the government, 43% thought only "completely safe" medications could be adver-

tised, and 22% believed that prescription drugs with serious side effects were restricted from advertisements. Additionally, there was a highly significant correlation between a positive attitude about DTC advertising and false confidence in how DTC advertising is regulated.

Data suggest that patients may not be upset with their physician for refusing to prescribe the advertised medication (9). Overall, the effects of television advertising on patient education and health appear mixed. On the one hand, advertisements may be unclear or misleading, while on the other hand, patients may be stimulated to seek additional information from a physician. More data are needed describing the effects of DTC-generated patient visits on doctor-patient communication, patient and physician satisfaction, and on health promotion and disease prevention activities.

Some important health concerns are addressed by DTC advertising, such as adjuvant treatment for smoking cessation and treatment of hyperlipidemia. However, as might be expected, pharmaceutical manufacturers' choices of drugs to promote appear to be governed by profit as well as by a desire to improve public health, and are limited to certain maladies and diseases. For the 12-month period ending March 1999, of the ten most promoted brands, three treated seasonal allergies, one treated male baldness, and one treated erectile dysfunction (1). Successful amelioration of these and other maladies may be important to individuals so afflicted, and pharmaceutical industry attention to symptom relief is worthy. We believe all medically recognized maladies are appropriate targets for advertising. However, the industry's choices of drugs to promote for certain maladies do not support the argument that DTC advertising serves as an important public health tool.

Major professional organizations have parallel positions on DTC advertising. The American Medical Association opposes product-specific DTC advertising of prescription medication (15). A review of several national organizations of pharmacists and the American Public Health Association found that all groups support educational advertising and all discourage medication-specific advertising (13).

### **Why DTC Prescription Drug Advertising Is Different from General Product Advertising**

DTC prescription drug advertising differs from general product advertising because of the

nature of the product and the nature of the targeted need. Health differs from typical consumer needs because: (a) health is a fundamental necessity; (b) the consumer often cannot adequately assess for the absence or presence of disease; (c) treatment requires specialized expertise; and (d) misdiagnosis, mistreatment, or nontreatment may have profound consequences. Furthermore, people who are ill are frequently rendered vulnerable to exploitation by their disease. DTC advertising targets persons with health conditions of sufficient significance to warrant physician assessment. Furthermore, these conditions are sufficiently serious to justify use of prescription medication, the subset of medications with the greatest potential for toxicity and drug-drug interactions.

DTC prescription drug advertising differs from general advertising because the former creates demand for a product: (a) that the consumer is poorly prepared to evaluate, (b) that may be inappropriate or harmful for the patient, and (c) to which consumer access is controlled by physicians.

### **Benefits and Harms of DTC Advertising**

Evidence suggests that DTC advertising may stimulate doctor-patient communication, at least for well-educated patients (8). Through DTC advertising, patients may seek health screening, become aware of health concerns overlooked by their physician, or may raise a treatment option not considered by the physician. New opportunities for patient education may be generated. Additionally, patient inquiry about advertised medications may induce doctors to keep abreast of developments in drug therapy. Patients who discuss information from DTC advertising with their physicians may have more frequent and productive communications with them. These visits may lead to query-specific care, as well as more broadly focused health activities.

On the other hand, DTC advertising tends to stimulate patient demand for specific medications. Since the physician's efforts must always be prioritized to important patient problems, the time for reeducating and reorienting their patients' conceptions regarding inappropriate medications may not be available. When the physician advocates nontreatment, in the patient's interest, the patient may suspect unjustified refusal or even deception. These interactions may distress both physicians and patients and compromise the trusting relationship they

have established. And, in this cost-conscious health-delivery environment, DTC advertising may exploit already-existing suspicion of physician interest. Further study of the doctor-patient dynamic is warranted to compare requests for specific medications with general or inexplicit requests for medications, and to compare the effects of DTC advertising on general health issues such as health screening interventions.

In some cases, DTC advertising can pose a health risk. Historically, after the release of a new medication, its use gradually increases, providing some opportunity to monitor adverse reactions. DTC advertising can generate tremendous early demand for a newly approved medication, which may expose large numbers of patients to as-yet unrecognized side effects. For example, in its first 8 months on the market, Viagra<sup>®</sup> sales reached \$608 million (16). Sales have slowed after complications in patients with coronary heart disease were recognized. Similarly, troglitazone, a new oral medication for diabetes, was widely promoted until cases of serious hepatotoxicity developed.

Competition to attract and retain patients may result in efforts to increase patient satisfaction, perhaps by a readiness on the part of the physician to accommodate patient requests for medication. These requests can then fuel tensions between the physician, the patient, and a managed care organization (when involved) (1). Here, physicians balancing responsibilities to their employer with obligations of patient advocacy, face yet another profit-motivated challenge to professional credibility.

DTC advertising may foster inappropriate medication use. Data suggest that patient demand motivates inappropriate drug prescribing (17, 18). Other data suggest that both patient expectation and physician perception of patient expectation for prescription medication correlate with the issuance of a prescription (19).

Furthermore, some DTC advertising is an affront to the traditional, albeit evolving, medical contract with society. Marketing to patients implies that physicians are deficient in their responsibilities to patients, and may underprescribe medications. Furthermore, the fact that the preponderance of marketing activity for some drugs is directed to consumers suggests a trend toward diminishing the doctor-patient relationship. The industry may claim it is promoting the doctor's role by directing patients to see a doctor. However, these patient visits result from consumer demand for a product "prescribed" by the manufacturer, not the

physician. The role of medicine in society and the relationship between patient and physician are worthy of reevaluation in the context of DTC advertising. However, such an analysis is beyond the scope of this discussion.

The data are clear that physicians often underutilize important medications (e.g., beta blockers for myocardial infarction, inhaled steroids for asthmatics). Variation in clinical practice is a well-recognized phenomenon, as Morris suggests, refractory to practice guidelines, educational initiatives and other interventions, because humans have a limited ability to incorporate information in decision making (20). This problem is large and complex. To our knowledge, however, there are no data showing that advertising to patients improves physicians' prescribing patterns, patient outcomes, or cost effectiveness of care. In fact, DTC advertising may lead to inappropriate and possibly harmful overuse of medications, as seen recently with heavily marketed anti-influenza medications (21).

A different kind of focus is on the horizon: pressure is slowly building for traffic in confidential medical information (22). Arguments supporting DTC advertising have been advanced to advocate targeted consumer advertising utilizing personal medical data. Some of the purported benefits of DTC advertising, i.e., patient education and better treatment choices and care, arguably, are more readily achieved if individual patients receive advertisements related to their own diagnosed conditions and current treatments. For example, a hyperlipidemic patient may receive information on lifestyle modification, medical treatment, and monitoring. However, such patients may also be poorly served. For example, a similar patient could receive advertisements promoting an antilipidemic medication as superior to the one prescribed for and being taken by the patient, leaving him or her confused and skeptical about the benefits of current treatment and the competence of the prescribing physician.

### **Business and Health Care Ethics**

Codes of ethics for health professionals recognize the inherent vulnerability of the patient and the tension between patient autonomy and appropriate physician paternalism. These codes direct physicians to advocate for their patients, protect their patients from harm, promote patient good, serve patients as their fiduciary, and be self-effacing where personal and patient interests conflict.

Business ethics operate from a different set of premises, many of them codified in laws and regulations. In terms of marketing, ethical obligations are generalized among the target population. For example, one may argue that DTC advertising is ethical because many consumers benefit from greater awareness of specific health conditions, whereas no one is harmed because physicians control drug prescribing. Patient-directed concerns within professional ethics may not register on scales of business ethics.

### Recommendations

The health benefits of DTC advertising can be achieved without many of the attendant negative effects. Public service messages describing important health conditions and their appropriate treatment(s) can better achieve the educational goals claimed by pharmaceutical advertisers. Such activity could stimulate patient-physician discussion without creating inappropriate demand, and without exacerbating tension between patients and the health system. One might argue that there is a public right to information about prescription medication. However, this information, divorced from obscuring promotional material, is widely available to consumers in innumerable books and internet web sites, from professional organizations, and from the Food and Drug Administration, as well as other governmental sources.

The Committee on Bioethical Issues of the Medical Society of the State of New York holds that DTC advertising, as presently conducted, is of unproved net benefit to the public, and may disadvantage patients and consumers. Some may argue that such advertising should not be restricted merely because of unproved net effect. But, historically, physicians have operated according to the dictum "primum non nocere." Physicians must advocate practices that unambiguously benefit their patients, whatever other social groups may endorse.

The committee therefore challenges the medical community and the pharmaceutical industry to reexamine their interrelating practices to better promote patient health and welfare. Specifically, the committee supports the following measures to improve consumer knowledge and patient care:

- It should be permissible for specific medications to be named in consumer promotions in regulated media only for nonduplicative

medications, and only in conjunction with clear educational content.

- Unsolicited patient-directed prescription advertising should be prohibited.
- We agree with recommendations to enhance the FDA's ability to sanction and its authority to enforce penalties for breaches of its advertising guidelines (23). If such ability is insufficient to modify practices, we support allocation of additional resources to make possible pre-screening and approval of advertisements by regulatory bodies prior to their release and distribution. Moreover, FDA scrutiny of advertisements directed toward health care professionals and published in professional journals is desirable, because consumers increasingly access professional journals for health information.
- Professional organizations should improve efforts to foster continuing professional education, disseminate literature on evidence-based medicine and current best practice, and quickly alert physicians to important new developments (good and bad), so that physicians are better able to provide patients with state-of-the-art medical information and care. Publications which regularly offer analyses of the benefits, risks, and costs of alternative drug treatments are invaluable resources.

Clearly, DTC advertising has not been adequately studied. To improve the factual basis for regulation, and to perhaps identify additional ways to improve health, we offer suggestions toward a research agenda:

- The physician-patient relationship: How does DTC advertising affect this dynamic? Is information sharing enhanced? Does physician unwillingness to prescribe advertised medications create suspicion or distress, or does it stimulate productive health encounters?
- Public and personal health effects: How does DTC advertising affect patients' health knowledge, health practices and other behaviors, including medication compliance? What assumptions do laypersons hold about DTC advertising in terms of regulations and restrictions for advertisers, accuracy, and completeness of information and product safety?

- Clinical practice: How does DTC advertising affect medication usage, health outcomes, health-care costs and cost-effectiveness of care? How does DTC advertising affect physicians' prescribing patterns and clinical practices?

### Conclusion

DTC advertising is yet another example of the challenges faced by consumers, physicians, and society as a whole, when powerful market forces confront health-care interests. While pharmaceutical companies serve a most valuable role in medical care, DTC advertising essentially is a profit-motivated activity of unproved benefit to the public. Public good requires that patients be educated, not exploited, and that professional integrity be maintained and supported. DTC advertising should be held to standards of accuracy, clarity and balance that will help realize these goals. Further studies are essential to assure that patients are being well served.

### References

1. IMS Health. [www.imshealth.com/html/news\\_arc/06\\_07\\_1999\\_211.htm](http://www.imshealth.com/html/news_arc/06_07_1999_211.htm)
2. Growth seen in ads for direct-to-consumer drugs. *Am Med News* Apr 27, 1998:16.
3. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352(n). Sect. 502(n) (1983).
4. Direct-to-consumer advertising of prescription drugs. 50 Fed. Reg. 36,677 (1985).
5. Nordenberg T. Direct to you: TV drug ads that make sense. *FDA Consum* Jan–Feb 1998. [www.verity.fda.gov/search97cgi/s97](http://www.verity.fda.gov/search97cgi/s97)
6. Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: Experts' assessments. *Ann Intern Med* 1992; 116(11):912–919.
7. Rothermich EA, Pathak DS, Smeenk DA. Health-related quality-of-life claims in prescription drug advertisements. *Am J Health Syst Pharm* 1996; 53:1565–1569.
8. Lipsky MS, Taylor CA. The opinions and experiences of family physicians regarding direct-to-consumer advertising. *J Fam Pract* 1997; 45:495–499.
9. Morris LA, Brinberg D, Klimberg R, et al. The attitudes of consumers toward direct advertising of prescription drugs. *Public Health Rep* 1986; 101:82–89.
10. Morris LA, Brinberg D, Klimberg R, et al. Consumer attitudes about advertisements for medicinal drugs. *Soc Sci Med* 1986; 22:629–638.
11. Schommer JC, Doucette WR, Mehta BH. Rote learning after exposure to direct-to-consumer television advertisement for a prescription drug. *Clin Ther* 1998; 20:617–632.
12. Tsao JC. Informational and symbolic content of over-the-counter drug advertising. *J Drug Educ* 1997; 27:173–197.
13. Cohen EP. Direct-to-the-public advertisement of prescription drugs. *N Engl J Med* 1988; 318:373–376.
14. Bell RA, Kravitz RL, Wilkes MS. Direct-to-consumer prescription drug advertising and the public. *J Gen Intern Med* 1999; 14:651–657.
15. American Medical Association. House of Delegates Policy, H-105.990 (1999).
16. IMS Health. [http://195.89.127.11/insight/report/world\\_market/launch.html](http://195.89.127.11/insight/report/world_market/launch.html)
17. Schwartz RK, Soumerai SB, Avorn J. Physician motivations for nonscientific drug prescribing. *Soc Sci Med* 1989; 28:577–582.
18. Hamm RM, Hicks RJ, Bembien DA. Antibiotics and respiratory infections: Are patients more satisfied when expectations are met? *J Fam Pract* 1996; 43:56–62.
19. Cockburn J, Pit S. Prescribing behaviour in clinical practice: Patients' expectations and doctors' perceptions of patients' expectations — a questionnaire study. *BMJ* 1997; 315:520–523.
20. Morris AH. Developing and implementing computerized protocols for standardization of clinical decisions. *Ann Intern Med* 2000; 132:373–383.
21. Food and Drug Administration. Medwatch, The FDA Medical Products Reporting Program. Public health advisory: Safe and appropriate use of influenza drug. January 12, 2000. <http://pharminfo.com/medwatch/mwrpt93.html>
22. Etzioni A. Medical records. Enhancing privacy, preserving the common good. *Hast Cent Rep* 1999; 29(2):14–23.
23. Terzian TV. Direct-to-consumer prescription drug advertising. *Am J Law Med* 1999; 25:149–167.