

Direct-to-Consumer Prescription Drug Advertising Builds Bridges Between Patients and Physicians

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DIRECT-TO-CONSUMER (DTC) ADVERTISING IS AN EXCELLENT way to meet the growing demand for medical information, empowering consumers by educating them about health conditions and possible treatments. By so doing, it can play an important role in improving public health.

"In health care, there is a general trend toward having consumers more responsible for their own health," according to Linda Golodner, president of the National Consumers League.¹

The sources of user-accessible information about health care have increased exponentially just in the past few years. More than 50 consumer magazines about health care appear on the newsstands every month. Many television stations have a physician dispensing medical news. Nearly one quarter of the Internet is devoted to health care information.² The *Physicians' Desk Reference*, once largely confined to physicians' offices, is now available in a consumer edition at pharmacy counters.

Along with these sources, DTC advertising is a key means of informing and empowering patients. *Prevention Magazine*, in a study based on a national survey conducted during the spring of 1998 with technical assistance from the Food and Drug Administration (FDA),³ found that:

- More than 53 million consumers talked to their physicians about a medicine they saw advertised, and an additional 49 million sought information from another source, such as the Internet.
- Thirty-eight percent of those who talked to their physicians about a medicine they saw advertised sought information about the product from at least 1 other source.
- Direct-to-consumer advertising "encouraged a projected 21.2 million consumers to talk with their doctor about a medical condition or illness they had never talked with their doctor about before seeing an advertisement."

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- As many as 12.1 million consumers received a prescribed drug as a direct result of seeing a DTC advertisement.

The *Prevention Magazine* study also found that DTC advertising may improve patient compliance with drug regimens. "Many consumers who have seen advertisements for medicines they are currently taking say the advertising makes them feel better about the medicine they're taking, makes them more likely to take it and reminds them to have their prescriptions refilled," the study stated. The study concluded that DTC advertising "may play a very real role in enhancing public health."

Because DTC advertising is so new, more studies are needed to determine more definitively its cost-effectiveness and its precise impact on improving outcomes and public health. The FDA is planning a survey of consumers who have recently visited a physician to ask their views on prescription drugs they have received and their behavior regarding prescription drug advertising.

Not surprisingly, spending on DTC advertising has accelerated since the FDA changed its guidelines in August 1997 to allow manufacturers who advertise prescription medicines on television more flexibility in providing information about the risks of the drugs. IMS HEALTH, a health care information company in Plymouth Meeting, Pa, expects spending on DTC television advertising to more than double in 1998, following a large gain in 1997.

According to IMS HEALTH, spending on DTC advertising increased 46% in 1997 (to \$917 million), while spending on promotion directed to physicians was about \$4 billion in 1997.⁴ In other words, companies spent more than 4 times as much promoting products to physicians as they spent promoting products to consumers.

Direct-to-consumer advertising that encourages millions of Americans to consult their physicians can help to improve pub-

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lic health because a number of leading diseases are underdiagnosed and undertreated. For example:

- An estimated 8 million undiagnosed cases of diabetes exist among adults in the United States.⁵
- Only about 10 million of the 30 million Americans with high cholesterol levels take cholesterol-lowering drugs.⁶
- Only 1 depressed person in 10 receives adequate medical treatment, and one third of people with major depression do not seek treatment.⁷
- Millions of Americans are estimated to have undiagnosed high blood pressure.⁸

For conditions such as these, which can be treated with prescription drugs, the consequences of not seeking appropriate treatment can be dire—for the individual, the family, and society. Untreated diabetes can lead to blindness or limb amputation. Unchecked high cholesterol levels can lead to heart attack or stroke, while cholesterol-lowering drugs can cut this risk by about 30%.⁹ Failure to treat depression can result in suicide, and high blood pressure can lead to stroke, heart attacks, and kidney failure.

Conversely, there is a growing body of evidence that increased use of pharmaceuticals will improve public health:

- The Air Force/Texas Coronary Atherosclerosis Prevention Study concluded that use of a cholesterol-lowering drug can lower the risk of heart attacks, chest pain, and cardiac arrest by 37%, even in people with no symptoms of heart disease. The authors of the study estimate that 6 million Americans currently not recommended for this treatment could benefit.¹⁰
- A study by the Agency for Health Care Policy and Research found that increased use of anticoagulant drugs would prevent 40 000 strokes a year.¹¹
- A study conducted at the University of Maryland Medical Center concluded that patients treated with β -blocker drugs after myocardial infarction were 40% less likely to die than those who do not receive the drug.¹² In a study from the National Cooperative Cardiovascular Project, only half the people who could be helped by a β -blocker following myocardial infarction were taking such a medicine.¹³

Direct-to-consumer advertising is a highly effective way to communicate the availability of treatments to the public. In 1992, the first DTC consumer television advertisement for a nicotine patch aired during the Super Bowl. According to the American Association of Advertising Agencies (AAAA), the public response was so great that, within weeks, demand for the patches exceeded the supply. The product had been available for months, but people who might have been interested in quitting smoking were simply not aware of it.

Advertising promoted widespread awareness overnight, prompted patient-physician conversations, and may have helped many people to stop smoking.¹⁴ John Kamp of the AAAA stated: "Government agencies and medical professionals can use their tools until they're blue in the face and not reach the people who will be reached through television."¹⁵ Similarly, according to data compiled by IMS HEALTH, patient visits to

physicians for osteoporosis nearly doubled in the 1-year period following the debut of DTC advertisements for a new drug for the disease. In the fourth quarter of 1995, there were 409 000 visits to physicians for osteoporosis. Advertisements for the new medicine started appearing at the end of 1995. In the fourth quarter of 1996, there were 713 000 physician visits by patients seeking help for osteoporosis.¹⁵

An advertising campaign for a medicine for genital herpes was launched in 1997. Some 45 million people aged 12 years and older in the United States are infected with the virus that causes this disease. In a survey by the manufacturer of the medicine, 49% of the patients who had called the toll-free telephone number in the advertisement saw their physicians within 3 months after seeing the advertisement. Fifty-one percent of these patients did not receive a prescription for the medicine, indicating that the physician decided a prescription was inappropriate, even though the patient had probably asked for one (Andrew P. Witty, Glaxo Wellcome Inc, Research Triangle Park, NC, unpublished data, December 1998).

Pharmaceutical companies have both a right and a responsibility to inform people about their products under the supervision of the FDA, which regulates prescription drug advertising. Companies are committed to responsible advertising that enhances the patient-physician relationship and encourages the appropriate use of prescription drugs under a physician's supervision. While such advertising prompts more people to seek professional help, it does not dictate the outcome of the physician visit or the kind of help patients eventually receive.

Direct-to-consumer advertising merely motivates patients to learn more about medical conditions and treatment options and to consult their physicians. Once the dialogue is started, the physician's role is preeminent. The patient has been empowered with information, not prescribing authority. In the words of Harvard Medical School Professor Jerry Avorn: "There's no detail man or pharmaceutical company or patient that puts a gun to a doctor's head to write a prescription. Ultimately, it isn't the patient's signature on the prescription—it's the doctor's."¹⁶

Participatory health care—consumers assuming more responsibility for their own health—is changing the nature of the patient-physician relationship. In a recent survey conducted by Yankelovich Partners, 95% of both physicians and patients described the ideal patient-physician relationship as a mutual partnership.¹⁷ Such a partnership can lead to better health outcomes through appropriate use of safe and effective prescription medicines that save lives, cure disease, and alleviate pain and suffering.

The mortality rate for the acquired immunodeficiency syndrome (AIDS) dropped more than 3-fold from 1995 through 1997, for example, due to the increasing use of combination antiretroviral therapy.¹⁸ Deaths due to heart disease decreased more than 30% during the 1980s, with 50% of the decline attributed to the use of new medicines.¹⁹ Antibiotics and vaccines have virtually wiped out such diseases as diphtheria, syphilis, pertussis, measles, and polio.²⁰ And there are

more than 1000 new medicines in development—for Alzheimer disease, cancer, heart disease, stroke, infectious diseases, AIDS, arthritis, Parkinson disease, diabetes, and many other diseases—promising even more effective treatments and better outcomes in the future.²¹

By greatly increasing the likelihood that patients will seek help for their medical problems and receive a safe and effective prescribed medicine, DTC advertising will, as the *Prevention Magazine* study stated, “play a very real role in enhancing public health.”

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Direct-to-Consumer Marketing of Prescription Drugs Creating Consumer Demand

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IN THE EARLY 1980S, THE PHARMACEUTICAL INDUSTRY BEGAN marketing prescription drugs directly to patients. The Food and Drug Administration (FDA) imposed a moratorium on this marketing strategy in 1983, then lifted it in 1985.¹ Since then, the industry has devoted increasing resources to this strategy. In a 1988 editorial on direct-to-consumer (DTC) marketing, Eric P. Cohen, MD, wrote, “Issues of regulation of advertising, cost, competition, public health, and individual well being need to be carefully examined.”² Examination of these issues in rigorous, independent studies has not occurred. Despite the lack of studies, the FDA has relaxed regulations governing DTC marketing of prescription drugs.³

Proponents hypothesize that DTC marketing, by providing educational information, is valuable, notifying consumers of new therapies and motivating them to seek care. However, the pharmaceutical industry, driven in part by financial motives, is providing information of suspect quality and thus

minimal benefit. Reckoning the costs, economic and otherwise, the public health value of DTC marketing is negligible. Moreover, the effects of DTC marketing are undesirable. Most important, by creating consumer demand, DTC marketing undermines the protection that is a result of requiring a physician to certify a patient's need for a prescription drug. For the benefit of patients, physicians, and the public's health, the FDA should consider stricter—not more permissive—regulations.

While providing educational information may be one of the industry's motives, the bottom-line desire for profit is undoubtedly another. In this respect, industry efforts have been successful. Advertising nicotine patches directly to consumers turned patches into “an \$800 million dollar category.”⁴ Aggressive marketing of Claritin (Schering-Plough, Madison, NJ) captured 56% of the \$1.8 billion nonsedating antihistamine

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