When Business and Practice Collide: Direct-to-Consumer Advertising
By Michelle Moomaw, Pharm.D.

It is nearly impossible today to turn on the television or read a magazine without seeing an advertisement for a prescription medication. CBS HealthWatch reported in 1998 that 66% of consumers in the United States had seen a particular product advertised in print, while 61% had seen one promoted on television. Spending on direct-to-consumer advertisements increased 212% between 1995 and 1996, reaching $595 million. By 1999 this figure soared to $1.3 billion. In response to this increase in advertising, between 1993 and 1998, 22% of the associated increase in retail sales for prescription drugs was for the 10 most heavily promoted medications. The most commonly advertised products are for treatment of chronic conditions including allergy, asthma, osteoporosis, arthritis, hypercholesterolemia, cancer, cardiovascular disease, and diabetes. With this significant upsurge in marketing prescription medications directly to consumers, questions arise regarding its effect on health care. This article will examine direct-to-consumer (D-T-C) advertising from the perspective of the pharmaceutical industry, the consumer, the practitioner, and finally the business of health care.

Although it seems that prescription medication advertisements have infiltrated consumer print and broadcast media only recently, D-T-C marketing of these products is not a new concept. The first advertisement for a patent medication appeared in a local newspaper in Boston in 1780. The modern age of advertising prescription medications began in the 1980s; up until this time, these products were almost exclusively marketed to physicians. In the 80s, newspaper and magazine advertisements targeted at the consumer began to appear starting with RufenR (ibuprofen) and PneumovaxR. This appeared to be a natural progression of events sparked in the 1970s when both the FDA and the public recognized the need for greater access to information about health care and related topics. Greater access to information allowed patients to be more involved in, and make informed decisions about, their own care.

In 1983 the FDA, realizing they had no established regulations specific for D-T-C advertising, requested a voluntary moratorium. Before proposing such regulations, the FDA wanted time to discuss and study these advertisements including their potential effect on patients and the health care system. In 1985, after two years, the FDA withdrew the moratorium stating that the same regulations that apply to advertisements directed toward physicians should apply to advertisements directed toward consumers. These regulations apply to product-specific advertisements, that is, advertisements that state the name of the medication, its indication, and safety and efficacy claims. Such advertisements are required to provide full disclosure of information and cannot be misleading. Advertisements are required to include a "fair balance" of information, meaning there must be discussion of both benefits and risks. The FDA also requires a brief summary of the package insert, including side effects, contraindications, precautions, and warnings. In lieu of this brief summary, advertisements can present "adequate

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In August 1997, the FDA clarified how the requirement for “adequate provisions” could be met in direct-to-consumer advertisements when they issued “Guidance for Industry: Consumer-Directed Broadcast Advertisements.” This guidance had the effect of relaxing the standards for advertisements directed at consumers relative to the standards for advertisements directed at health care professionals.2

Touting the educational value of the information provided, the pharmaceutical industry advocates D-T-C advertising. By all measures, the cost of this investment in education is astounding, as are the potential payoffs for the pharmaceutical industry. By one estimate, a $50 million commitment to D-T-C advertising is needed to produce a difference in pharmaceutical sales.4

Nicotine patches reached the $800-million product category after D-T-C marketing.7

provisions” to obtain this information. The regulations also outline requirements for type size, color, and readability.2,5,6

These regulations appeared to be adequate for print media, and prescription medication advertisements began to emerge in a variety of consumer newspapers and magazines. Given the time constraints of television and radio advertisements, compliance with the regulations was difficult. In August 1997, the FDA issued “Guidance for Industry: Consumer-Directed Broadcast Advertisements,” clarifying how the requirement for “adequate provisions” could be met in these advertisements.2,4-6,8 The FDA stated broadcast advertisements must still have full disclosure, fair balance, and must contain a statement regarding the “most important” risks associated with a medication in either the audio, or audio and video, portion of the advertisement. However, instead of a brief summary of the prescribing information, the advertisement could inform the patient how to obtain this information by including a toll-free phone number, the address to an internet web site, reference to a print ad, and by stating that further information could be obtained through a doctor or pharmacist.5,6 With the release of this guidance, the public has witnessed a proliferation of advertisements on television and radio for products ranging from the treatment of allergies to the treatment of impotence.

The pharmaceutical industry advocates D-T-C advertising, touting the educational value of the information presented in these ads. The industry has put forth the view that D-T-C advertisements offer the opportunity to provide patients with valuable information regarding disease states, treatment options, and safety information of certain products, while encouraging patients to seek care and further information from their health care practitioner. This, however, is only one aspect of the issue. Although pharmaceutical companies provide needed products to better the health of the consumer, their bottom-line goal is profit.7 With the advent of managed care organizations and restrictive formularies, marketers have found it increasingly difficult to reach prescribers directly. Simply put, the goals of D-T-C advertising are to educate the consumer about a product, persuade that consumer to act on the information provided, and ultimately increase practitioner prescribing for that product.9 Companies have discovered that by targeting consumers, they can create consumer demand and increase sales. It has been estimated that it requires a $50 million investment in D-T-C advertising to produce a difference in sales.4 It is apparent from the ever-increasing expenditures that this marketing strategy is effective in some arenas. If the advertisements were ineffective, companies would not spend the money or the time required for this marketing. Claritin® (Schering-Plough) captured 56% of a $1.8 billion market after aggressive D-T-C advertising.7 Through D-T-C advertising, companies hope to increase brand recall, brand loyalty, and sales volumes.6

Despite the increased market share and associated profit, a few concerns arise regarding D-T-C advertising that relate to the pharmaceutical industry. The first concern is in regard to increasing expenditures on marketing. Who is going to ultimately pay? The answer to this question is somewhat theoretical and market dependent. If there are several products being marketed, D-T-C advertising may increase competition, thus driving down the prices of the advertised and competing products. On the other hand, if it is a sole product being marketed, the increased spending on advertising may be passed on to the consumer through inflated retail prices.1 The second concern is a question of liability. Pharmaceutical companies have traditionally been protected from liability claims through the concept of a “learned intermediary” (i.e., the prescriber).2 With the pharmaceutical industry increasingly marketing directly to consumers, this defense becomes questionable. Presumably, it is only a matter of time before the courts decide this issue.

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In general, surveys show the public views D-T-C advertising in a positive way. Predictably, awareness of D-T-C product advertising, a measure of the effectiveness of the marketing strategy, is greatly increased if the consumer has the targeted medical condition.1

- 43% percent of consumers thought that only “completely safe” products could be marketed directly to consumers.10
- 22% believed that advertising of medications with “serious side effects” had been banned.10

One consumer cohort was aware of 3.7 out of 10 advertised products. Women and people >50 were most likely to pay attention to ads.1

A survey conducted by Prevention Magazine revealed that 63% of consumers recalled seeing an advertisement for a prescription drug. Of these:

~1/3 spoke to their physician about a medical condition or medication advertised
~1/4 asked their physician for a specific product

Of those who inquired specifically, 80% received the prescription requested.

There remains some controversy over how clear D-T-C advertisements convey information and if typical consumers have the ability to understand and apply the information to better their own health. One study reported that 63% of consumers did not believe they could tell if they were being misled by an advertisement.7 Another study showed that benefits were recalled much more frequently than the risks and that patients commonly misinterpret the risks.6 Misconceptions regarding the regulation of D-T-C advertisements are also common among consumers, possibly further hindering their ability to critically analyze the information presented. Fifty percent of consumers thought that D-T-C advertisements had to be approved by the FDA prior to publication or broadcast. In addition, 43% thought that only “completely safe” products could be marketed directly to consumers, and 22% believed that advertising of medications with “serious side effects” had been banned.10

Given that this advertising is directed primarily at the consumer, the next logical step is to examine how the consumer perceives these advertisements and what impact the ads have on those consumers. In general, surveys show the public views D-T-C advertising in a positive way. Starting several decades ago, patients expressed a desire to become more involved in, and more educated about, their health care. This is especially true today. The increased availability of information has empowered consumers and enabled them to be active participants in their own care. Consumer advocates for D-T-C advertising cite multiple benefits of this practice.6 They support the idea that the information provided improves the consumer’s ability to make educated health care decisions. Theoretically, advertisements may help increase awareness about new therapies and equivalent treatments. D-T-C advertising can also serve to arm patients with information about their health and encourage them to practice preventative health measures.6

A study conducted in California analyzed the type of consumer reached by D-T-C advertisements, as well as how their behaviors were affected by the ads.1 On average, the consumer cohort studied was aware of 3.7 out of 10 advertised products. Women tended to be more aware of advertising than men, and people over 50 were also more likely to pay attention to these ads. Awareness of product advertising was greatly increased if the consumer had a medical condition related to the advertised medication. In general, persons taking other medications, those in poorer health, those who had better health coverage, and those with a higher education level were more likely to recall product advertisements.

In 1997, Prevention Magazine, in association with the American Pharmaceutical Association, conducted a survey of readers examining the perception of, and the effects of, D-T-C advertisements.1,6,9 The survey revealed that 63% of people polled recalled seeing a prescription drug advertisement. However, 34% of those people didn’t remember what product the advertisement promoted and another 34% couldn’t remember the medical condition associated with the advertised medication. Although consumers stated that in general they did not feel the advertisements were clear or useful, about 1 in 3 spoke to their physician about a medical condition or medication advertised, and 1 in 4 asked their physician for a specific product by brand name. Of those who inquired specifically, 80% received the prescription requested. An FDA consumer survey in 1999 showed an even greater response to D-T-C advertising.10 In this survey, 3 of 4 patients polled recalled having seen or heard an advertisement in the past 3 months, and 1/2 of these patients sought more information about an advertised product. Fifty percent of those consumers who spoke to their physician received a prescription for the advertised medication, while 32% received a prescription for some other medication.

Direct-to-Consumer Advertising (continued)
Four of five family practitioners surveyed listed D-T-C advertising as “not a good idea.”

Costs and misinterpretation of information are concerns.

Up from 45% in 1989, in 1992 physicians reported 88% of patients asked for a drug by brand name. 7

At its worst, D-T-C advertising could lead to patients “shopping around” for practitioners willing to yield to requests to prescribe advertised medications. Indeed, in one survey 15% of consumers polled said they may switch to a new physician if their current physician refused to prescribe a requested medication. 1

Regardless of the net impact of D-T-C advertising on public health, it is clear that such advertisements are here to stay. The question at hand is how can health care practitioners harness the increase in consumer-directed medical information to improve patient care.

The third component in the D-T-C advertising equation is the practitioner. In 1992, physicians reported 88% of patients asked for a drug by brand name. 7 This number was only 45% in 1989. Not surprisingly, according to the literature, most practitioners view D-T-C advertising negatively. In a recent study of family physicians, 4 out of 5 believed D-T-C advertising was “not a good idea.” 1 Many practitioners are concerned that advertising is misleading and biased and will only serve to increase the cost of medications. In another survey, 39% of physicians thought D-T-C advertising caused patients to reach incorrect conclusions about medications. 2 In this age of increasingly “managed” care, physicians are unable to allot as much time with patients as they may wish. D-T-C advertising could compound this problem by increasing the proportion of time that practitioners spend dispelling medication misconceptions and realigning drug therapy expectations to be realistic. 9

The most detrimental effect D-T-C advertising may have is to distort or strain the relationship between practitioners and patients. In 1997, a study revealed 95% of physicians had encountered patients exposed to D-T-C advertisements. 4 Eighty-nine percent of physicians expressed disagreement with the statement that D-T-C advertising enhanced practitioner/patient relationships, and 71% agreed that these ads pressured physicians to prescribe medications they may not ordinarily prescribe. 4 When consumer demand is considered in the scenario it alters the relationship from practitioner/patient to practitioner/consumer. 7 This altered association may strain the relationship when practitioners feel pressured to prescribe certain medications. If the practitioner complies and prescribes the requested medication, it may not be in the best interest of the patient. If the practitioner refuses to prescribe the requested medication, it may be in the best interest of the patient, but the practitioner must then defend that decision. At its worst, D-T-C advertising could lead to patients “shopping” for practitioners who will yield to their demands. 1, 2, 4, 7 In the California study, 1 patients were asked how they thought they would react if their physician refused to prescribe the medication requested: 24% said they might try to obtain the prescription from another physician; 15% said they may switch to a new physician. In the end, D-T-C advertising could harm patient care, lead to overly expensive therapies, treatments that are less than optimal, or erode the professional effectiveness of practitioners.

The final issue to investigate is the effect that D-T-C advertising has on the structure of the health care system and on the resulting general public health. Today, more and more patients’ medication expenses are at least partially “managed” through managed care organizations and/or “pharmacy benefits” managers (PBMs) employed by insurance companies. Understandably, since they are charged with holding down drug costs for insurers, such “benefits managers” are discontented with the increase in D-T-C advertising. 5 Managed care organizations and PBMs feel that they are being forced to add agents to their drug formularies to maintain patient satisfaction and observe rising drug budgets as the result. 1 A leading PBM recently reported a 38.5% increase in per-member-per-year utilization of antihistamines. 6 This increase was driven mainly by the use of Claritin R (Schering-Plough), Zyrtec R (Pfizer), and Allegra R (Hoechst Marion Roussel), all heavily consumer-marketed products. Such a shift away from low-cost generic versions of brand name prescription drugs bear huge cost implications. In 1998 the average price of a generic prescription was $17.33, while the average price of a brand name prescription was $53.51. 4 D-T-C advertising has also increased demand for so called “lifestyle” drugs such as Viagra R (Pfizer) for which insurers previously have not provided a prescription benefit. 1 One view holds that the primary purpose of D-T-C advertising is to pressure managed care organizations into altering their drug formularies. 2
Another potential concern in response to D-T-C advertising is that it will lead to an overmedicated society by fostering the thought that there is a “pill for every ill.” Increased consumer interest in advertisements leads to increased physician visits, increased diagnostic tests, and increased health care expenditures. The question remains whether or not these advertisements are cost-effective. Expensive medications are being used to treat low-risk patients with mild disease or cosmetic concerns. Advocates of D-T-C advertising have a different outlook, stating that these advertisements lead to more health-conscious consumers that take better care of themselves, identifying medical conditions early, and partnering with physicians to achieve improved outcomes. It is yet to be determined if the net effect of D-T-C advertising on public health is positive or negative.

In summary, at its best, D-T-C advertising can help to increase patient awareness of disease states and treatment options, encourage better communications with primary care providers, and result in a net improvement in public health. However, there is some inherent risk in the increase of D-T-C marketing. These risks include strained patient/practitioner relationships, overmedicated consumers, increased health care costs, and potential harm to overall public health. Questions remaining about the impact of D-T-C advertising will only be answered when funds are allocated to perform studies of the effects of these advertisements on health care outcomes.

Regardless of the effects of D-T-C advertising, it is here to stay. Modern society demands access to information; D-T-C advertising is simply one way this demand is being met. Dwarfing the growth in D-T-C advertising and compounding the impact is the increasing importance of the internet as a source of medical information. The question at hand is really: How can health care practitioners harness this expanding interest in consumer-directed medical information to better care for patients? It can be argued that the internet, in conjunction with D-T-C advertising, can be viewed as an opportunity to improve communications between providers and patients. With expanding access of health care information to patients, practitioners have the option to become trusted educators, assisting patients in locating reputable information sources and facilitating evaluation in the proper context. An excellent internet resource to recommend to patients is the new National Library of Medicine’s Medlineplus (www.nlm.nih.gov/medlineplus) internet site. Several web sites complementary to the MedlinePlus site are listed to the left (see sidebars). Practitioners should consider embracing new opportunities to educate patients about medical conditions, treatments, and preventative health measures, thus leveraging the interest stimulated by D-T-C advertisements to improve patient knowledge and ultimately enhance the well-being of society.

References

Note: The editor gratefully acknowledges the assistance of Cindi Brennan, Pharm.D., and Daniel Lessler, M.D., in reviewing this article.
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<td>Crotalidae Polyvalent Immune Fab (ovine) (CroFab™)</td>
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* Refer to product labeling for full prescribing information.

One-Stop Shopping for Health Information on the Internet: MEDLINEplus

(Extract from a Press Release Dated January 26, 2001)

“We realize how important it is for people who search for information on the web, for their personal health and that of their families, to be able to go to a site they trust,” said Donald A.B. Lindberg, M.D., director of the National Library of Medicine.

Every weekday morning the home page of medlineplus.gov (that’s the complete address) will be updated with health-related articles selected from the Associated Press, New York Times Syndicate, and United Press International. They will not only be listed on the home page, but each will be linked to one or more of the 430 “health topics” within MEDLINEplus. Thus, for example, someone interested in diabetes will find a section called “Latest News” at the top of the diabetes page.

In addition to the “health topics” on individual diseases and medical conditions, the site also has an extensive medical encyclopedia with thousands of illustrations, detailed information about more than 9,000 brand name and generic prescription and over-the-counter drugs, a medical dictionary, directories of doctors and hospitals, and links to Clinicaltrials.gov, the NIH web site listing more than 5,000 clinical studies. There are even links to the scientific database, MEDLINE, so that the user can have access to the latest published research. MEDLINEplus draws on the extensive resources of the National Institutes of Health and other reliable, non-commercial sites. No registration is ever required for MEDLINEplus users.

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