American Journal of Pharmaceutical Education **2004; 68 (3) Article 66.**

TEACHERS' TOPICS

Direct-to-Consumer Prescription Drug Advertising and Pharmacy Practice

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Submitted August 28, 2003; accepted November 5, 2003; published July 27, 2004.

The *American Health Care Systems* course, PHBAS 410, at the Mylan School of Pharmacy of Duquesne University consists of class sessions involving the use of nontraditional, active-learning approaches to supplement an otherwise traditional lecture format. Usually, 2 to 3 class sessions are reserved for special topics during which issues facing contemporary pharmacy practice are discussed. One such topic discussed in the Spring 2002 course offering was the marketing of prescription drugs directly to consumers (DTC advertising). While much has been opined about this phenomenon, students in the course are encouraged to make informed decisions about patients' medication therapies and to use DTC advertising as an opportunity to promote patient safety. Students are provided some background information on various market factors and on the history of DTC advertising to facilitate their understanding of its ubiquity.

Keywords: advertising, health care system, marketing, direct-to-consumer advertising

INTRODUCTION

A number of legal and market-driven factors have facilitated the proliferation of advertisements for prescription drugs marketed directly to consumers. Direct-to-consumer (DTC) advertising of prescriptions drugs may impact patient attitudes, patient-provider communications, and ultimately, medication use. While both proponents and opponents of DTC advertising abound, pharmacists should seize opportunities for increased patient communication that result from this phenomenon. This lecture is presented to students in the *American Health Care System* course to provide some historical background and point out the realities in today's market for prescription medications in hopes of fostering their ability to evaluate DTC advertisements and promote the welfare of patients. The objectives for this topic are as follows:

1. Define DTC advertising and briefly discuss its historical evolution.
2. Identify various therapeutic classes and specific drugs being promoted through DTC advertising.
3. Discuss factors facilitating the growing use of DTC advertising by pharmaceutical manufacturers.
4. Distinguish among various types of DTC advertisements.
5. Discuss the FDA's revised guidance facilitating the widespread use of broadcast media in DTC advertising.
6. Define the terms, "brief summary," "major statement," "fair balance," and "adequate provision."
7. Discuss potential positive and negative consequences of DTC advertising.
8. Identify opportunities for pharmacists to enhance communication with patients and boost their practices as a result of DTC advertising.

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INSTRUCTIONAL METHODS

American Health Care Systems (*AHCS*) is a required 2-credit course offering students an introductory examination into issues of health care access and policy, particularly as they relate to pharmacy care and medication use. It is offered during the spring semester of the fourth year in a 6-year (0–6), entry-level PharmD curriculum. The course comprises components in professionalism, models of health care delivery, managed care, pharmacy benefits management, Medicare and Medicaid, and the roles of pharmacists in various practice settings. While over half of the class meetings involve traditional lecture, several active-learning strategies are used. Students make presentations on selected topics such as international health care systems and the use of technology in health care. The course is affiliated with the second-professional-year service-learning requirement. While listed as separate courses, the AHCS course was pared down from 3 to 2 credits to accommodate the service-learning experience, which deals primarily in issues of policy, access, and the role of non-

profit associations in public health. Additionally, a few classes in AHCS are set aside for students to engage faculty members in question-and-answer sessions, or for a faculty member's presentation of a special topic.

Special topics are typically reserved for the latter 2 to 4 class meetings. The subject matter of the special topics classes is sometimes decided upon in advance of the course being offered; however, the topics may be reevaluated and changed during the course. Prior to their engagement in special topics, students have acquired background knowledge in health care delivery, structure, organization, and financing. Having achieved at least a cursory understanding of the influences of managed care, governments, and the flow of money throughout the system, students are better prepared to evaluate information presented in special topics. Special topics issues over the past few course offerings have touched upon issues such as health care reform, systems quality initiatives, the Health Insurance Portability and Accountability Act (HIPAA), and (DTC) prescription-drug advertising.

The spring 2002 offering of the *AHCS* course included two 50-minute class meetings on DTC advertising. The first 50-minute session and 30 minutes of the latter session followed a traditional lecture format. Students were afforded the opportunity to ask questions about DTC advertising for 20 minutes during the latter session. Students were not provided or shown samples of DTC advertisements to evaluate and were not assigned outside projects related to DTC advertising. They did complete a reading assignment describing a drug manufacturer's travails with the Food and Drug Administration (FDA) in its attempt to market a lower (and arguably less than optimal) dosage strength of an antihistamine so that it may market it as "non-sedating" when higher, more effective doses caused some sedation.[1] Students were tested on the factual material presented in the lectures using a multiple-choice question format. Students were not given the opportunity to evaluate specific class meetings held on DTC advertising; however, a few students provided some commentary on the qualitative portion of the instructor's Teaching Evaluation Questionnaire (TEQ). Sixteen of the 113 students enrolled in the course participated in a study conducted by the author evaluating the content of print DTC advertisements in an independent study project; however, such participation was voluntary and was not in any way associated with the *AHCS* course.

Background

Pharmacists practice within a complex health care system. This partly privatized yet partly government-sponsored and controlled system creates conflicts in demand from various stakeholders with whom pharmacists routinely interact. As states contemplate initiatives to reduce spending on prescription drugs in their Medicaid programs and as the Federal government wrestles with a new Medicare prescription drug benefit, it is all but guaranteed that the system will only grow more complex.

Pharmacists already face several barriers and challenges to the practice of pharmaceutical care. Providing an additional challenge is direct-to-consumer (DTC) prescription drug advertising. Aside from occasional visits from pharmaceutical sales representatives, pharmacists have not been significant players in the prescription drug marketing process; however, they now face an informed public actively seeking questions about drugs they have seen or heard advertised in the mass media. While DTC advertising carries with it additional challenges and responsibilities, it presents pharmacists with opportunities to act as patient advocates and secure their trust through communication.

A DTC advertisement has been defined as "any promotional effort by a pharmaceutical company to present prescription drug information to the general public through the lay media, ie, newspapers, periodicals, television and radio."[2] Given the availability of information that can be accessed by professionals and lay consumers, this definition may appear somewhat dated; however, it correctly infers that a communication is an "advertisement" by its intent to have a direct effect on the behaviors of the end-user.

Pharmaceutical manufacturers raised the issue of advertising to consumers during the early 1980s. Eli Lilly & Company developed a publicity campaign for *Oraflex*, an arthritis drug, in 1982. Subsequently, Merck, Sharp and Dohme promoted *Pneumovax* with a tear-off coupon, and Boots Pharmaceuticals performed an intense advertising campaign for its *Rufen* brand of prescription-strength ibuprofen.[3] For several reasons, however, DTC advertising did not really catch on in the 1980s or early 1990s.

After its somewhat inauspicious beginning, DTC advertising has now pervaded print and broadcast media. The 1990s saw exponential growth in spending on DTC advertising. Total media spending increased from $55.3 million in 1991 to an estimated $2.5 billion in 2001.[3,4] Still, DTC advertising takes up only about 15% of advertising expenditures by United States pharmaceutical manufacturers, and its use is largely confined to a relatively small number of products.[3] Additionally, the growth in DTC spending has begun to slow as limitations to its effectiveness for certain product categories is being realized.[4]

Table 1. Factors responsible for the proliferation of DTC advertisement campaigns

Industry forces
Limitations faced by traditional marketing practices
Competitive forces in the pharmaceutical industry
Market forces
Changes in market structure/managed care
Consumerism movement in health care
Focus on functional quality as an outcome
Positive return on advertising dollars spent
Government forces
Changing regulatory climate

While the statistics fluctuate from year to year, products frequently advertised in 2001 included: *Vioxx*, *Claritin*, *Prilosec*, *Viagra*, *Xenical*, *Paxil*, *Celebrex*, *Propecia*, and *Zyrtec*,[5] although recent and potential future switches from prescription to nonprescription status for some of the products will change the nature of their promotion. Conditions for which DTC advertising is most frequently employed include arthritis, allergy, asthma, and erectile dysfunction.[5] DTC advertising is believed to be most effective when targeting conditions regarded as less complex or those with more overt deleterious effects on quality of life.[6] However, recent campaigns for drugs used in chemotherapy, and for patients with heart disease and hyperlipidemia would suggest that manufacturers believe that patients' influence may be expanding.

Factors Facilitating the Use of DTC Advertising

Factors responsible for the growth of DTC advertising can be summarized within the context of industry, market, and government forces (Table 1). Certain industry forces may have rendered traditional "detailing" somewhat less effective for certain product classes. Layers of bureaucracy associated with the United States health care system have limited physicians' time for obtaining continuing education credit, reading professional journals, and visiting with pharmaceutical sales representatives,[7] making the detailing of newer products especially difficult.

The pharmaceutical industry has witnessed heightened competitiveness in recent years. While modern technology has facilitated rapid growth in the number of new drugs being marketed, manufacturers may find it more difficult to rely on older "cash cow" drugs that turned a profit for decades. The window of opportunity for manufacturers to turn a profit on a new chemical entity may be shortened, making DTC advertising useful during the early part of the product's lifecycle.

Market forces outside of the pharmaceutical industry have also had a significant impact on manufacturers' promotional strategies. The autonomy and prescribing authority assumed by physicians has eroded in recent years with the proliferation of managed care and tighter controls by government payers. Physicians' choices of drug therapies are limited by formularies, protocols, prior authorizations, and other managed care tools. Since inclusion in formularies is so critical, health plans and employer benefits coordinators exert much influence on medication use. As such, pharmaceutical manufacturers see these stakeholders and members of pharmacy and therapeutics committees as the new targets for "detailing." Because pharmacy benefits are so important in health plan selection, disenrollment may ensue among employees who are unhappy with certain aspects of the employer's pharmacy benefit, such as its formulary.[8]

This is not surprising given the rising tide of consumerism in health care. Consumers "want to share in the decision-making about treatment and think it is acceptable to raise questions that suggest erosion of the physician's power."[9] Armed with the Internet and information from a plethora of sources, consumers of medical care have become more savvy and demanding. Consumerism in health care is abetted by the proleterianization of medical professionals,[10] which suggests that consumers may no longer view health professionals' wisdom as omniscient. Pharmaceutical manufacturers, aware that consumers seek empowerment and are emboldened to make specific requests from physicians, advertise directly to consumers in hopes that those requests will be for their products.

Patients desire therapies that help them to feel better and to perform their normal social roles.[11] Practitioners acknowledge that clinical end points alone do not suffice as appropriate measures of therapeutic effectiveness. Functional outcomes are recognized as appropriate goals of medication therapy. Many DTC advertising campaigns appeal to consumers' desires to enhance or maintain the lifestyles they had when they were younger and/or symptom-free.

Perhaps most importantly, DTC advertising may work effectively to stimulate drug sales. Research has demonstrated the success of DTC in raising consumers' brand awareness, likelihood of making specific product requests, and prescribers' propensity to comply with these requests.[4] While some DTC advertising campaigns have not yielded the kind of results their sponsors had hoped for, such advertising may still result in a positive return on the dollars spent.[4] The reality is that it is difficult to quantify the effectiveness of DTC advertising, as

Table 2. Types of DTC Advertisements for Prescription Drugs

(1) Reminder advertisements
- Mention the proprietary name of a drug product with little additional information.
- Limited in use following the FDA's 1997 draft guidance, however offshoots of these advertisements, wherein manufacturers promote their contributions toward the public's health, may generate recognition and goodwill.

(2) Help-seeking advertisements
- Provide a list of signs or symptoms and/or a set of factors that may predispose an individual to being susceptible to a particular condition.
- Notify the consumer that treatment/prophylaxis is available for the condition.
- Effective in promoting drugs for conditions for which many people are unaware that viable drug treatment is available or other drugs early in the product life cycle.
- Commonly employed in print media.
- Potentially the most beneficial type of DTC advertisement in improving health outcomes.

(3) Product-claim ("product-specific") advertisements
- Mention the proprietary name of a product and its indication(s).
- Must comply with 1997 DTC advertisement guidance rules established by the FDA.
- Commonly employed in various types of media.

Adapted from Bradley LR, Zito JM. Direct-to-consumer prescription drug advertising. Med Care. 1997;35:86-92.

changes in sales can be the result of any number of influences, not the least of which is the concomitant use of other promotional strategies by manufacturers.

Government forces have also shaped the implementation of DTC prescription drug marketing. In addition to the aforementioned controls over physicians' prescribing authority, the proliferation of DTC advertisements, particularly those on broadcast media, would not have been possible if not for the relaxation of certain rules by the FDA amidst a changing regulatory climate.

Regulation and Types of DTC Advertisements

Soon after manufacturers began to use DTC advertising in the early 1980s, the FDA called for a voluntary moratorium on this practice to allow the agency to conduct research on its likely ramifications.[12] The FDA found that consumers desired the information in DTC advertisements and were generally in favor of DTC advertising.[13] The FDA believed that DTC advertisements would be capable of effectively communicating risk and benefit information to consumers, though print media would be more effective than television.[14]

The FDA lifted its moratorium in 1985 with notification in the Federal Register.[15] However, this notice advised manufacturers that DTC advertisments aimed at the lay public had to abide by the same rules governing advertisements geared toward health professionals. Among these rules was a requirement that advertising of specific products by name ("product-claim" ads) include the product's brief summary, or prescribing information encompassing indications for use, dosing, side effects, warnings, contraindications, and pertinent interactions. Additionally, it was required that DTC advertisements not mislead or provide false information, and thus present a fair balance between claims of safety and efficacy and statements of relevant risks and limitations in effectiveness.[12]

These regulations made it difficult to air product-claim advertisements on broadcast media. Advertisers circumvented these regulations by producing advertisements that did not include the name of the product and its indication, simultaneously.[2] These so-called "reminder ads" stated the drug's proprietary name and flashed the manufacturer's logo, then advised the consumer to consult a prescriber. Alternatively, a narrator mentioned a set of symptoms or factors predisposing an individual to a disease state without mentioning a specific product and encouraged consultation with a prescriber ("help-seeking ad"). Table 2 lists and describes the use of 3 types of DTC advertisements.

The FDA heard complaints that the advertisements, particularly the reminder advertisements, were not informing the public to make rational decisions. In fact, they were confusing most consumers.[12] An advertisement that typified this genre was one for Hoescht Marion Roussel's *Allegra* in 1996, which depicted a woman windsurfing through a field of wheat. The FDA demanded that it be pulled because consumers were able to figure out from the advertisement that *Allegra* was meant to treat allergies.[12]

The FDA held a public hearing in October 1995 on DTC advertising to solicit advice from health care professionals, researchers, and consumers. From the information gathered then and subsequently, the FDA issued a new guidance for broadcast DTC advertisements.[12] The guidance stated that product-claim advertisements

Table 3. Sources for Additional Information That Must Accompany DTC Advertisements in Broadcast Media

- A statement that health professionals can provide additional information about the drug and disease state or condition
- A toll-free number for obtaining the product labeling information by mail, fax, or telephone
- A reference to one or more print advertisements or brochures
- A Web site address

could fulfill brief summary requirements by including a major statement on the important risks of the drug and mechanisms of adequate provision for the dissemination of all approved product labeling. Compliance with adequate provision requires that the advertisement provide additional sources (Table 3) for information about the product, the rationale for which is to appeal to consumers varying in literacy, access to technology, and propensity to seek information.[12]

Putative Pros and Cons of DTC Advertising

The putative pros and cons of DTC advertising are summarized in Table 4. Health care practitioners and professional organizations have demonstrated ambivalence or skepticism toward the effects of DTC advertising.[2,3] Perhaps the most commonly voiced concern is in regard to its potential effects on prescribing patterns. Practitioners fear that DTC advertising interferes with existing communications between them and patients and may jeopardize the patient-provider relationship.[3] Physicians believe that patients may switch providers if their demands for specific therapies are not met.[16] Pharmacists also may be faced with patients who raise questions about drugs they have seen advertised and who are determined to hear what they want to hear about the drug.

Another commonly cited concern over DTC advertising is that consumers are unable to discern the risk information presented in the advertisements. Patients may request certain products in spite of contraindications that may preclude use of the drug in their regimen. Research has demonstrated that consumers' retention of risk information presented in a print DTC advertisement was suspect and that those who were familiar with the advertisement had a false sense of knowledge about the disease that the product is intended to treat.[17] This is of particular concern for advertisements on broadcast media, when considering some consumers' belief that only the safest drugs are advertised on television.[3]

It has been argued that the goals of advertising are simply incongruent with the goals of health education.[2,18] Consumers may tend to respond with greater acuity to the promotional rather than the educational portions of advertised messages.[19] One in 3 consumers reported not noticing the "small print" information in print advertisements for nonprescription products, and only 34% of those who did take notice took the time to read it.[20] DTC advertisements contain numerous "persuasive" or noninformative components.[21] Another study suggested that even the informative components among many advertisements are shrouded within argumentative contexts (eg, "Now introducing the first drug for ['X' disease state] taken only once daily").[22] Physicians have the opinion that DTC advertisements equally inform and confuse patients, with only 16% of physicians respondents in one survey indicating that they do more good than harm.[4]

Table 4. Putative Pros and Cons of DTC Advertising

Pros-DTC advertising may

- Help meet consumer demands for information
- Educate consumers about treatment options for conditions they thought untreatable
- Encourage patients to seek medical attention and prompt earlier detection of disease
- Open up channels of dyadic communication
- Stimulate patients to be more involved in health care decision-making
- Decrease health care costs in the long-run

Cons-DTC advertising may

- Alter physician prescribing patterns
- Jeopardize the provider-patient relationship
- Engender a false sense of knowledge about diseases among consumers
- Engender a "pill-for-every ill" mentality
- Devalue non-pharmacological therapy
- Increase patients' exposure to unnecessary risks
- Increase drug therapy costs

There is concern that the continuous proliferation of messages that "new" and "better" treatments exist may have Americans regarding themselves as somewhat invincible to many conditions and may engender a "pill for every ill" mentality.[2] Americans may also desire quick relief for conditions that require no drug therapy or for which therapy is either unavailable or not cost-effective.[2] Such a mentality could result in a devaluation of nonpharmacological therapy and heighten a sense among many individuals that diet, exercise, and other preventative health-related activities are relatively inconsequential.[2]

Perhaps most importantly, pressure from patients to obtain prescription drugs from prescribers may expose

patients to unneeded drug therapies and all of the associated risks (eg, adverse effects, drug interactions).[4] There exists many situations wherein medications represent only an additive cost; for example, the cost of having every American with elevated cholesterol levels take a drug for extended periods may exceed the benefit derived compared with nonpharmacological interventions.[4] The resulting untoward effects and the greater use of more expensive therapies in general may add to upwardly spiraling prescription drug costs. Promotional spending has been blamed for much of the recent inflation in prescription drug prices,[3] and while DTC advertising represents only about 1 in 6 to 7 promotional dollars spent, its growth has been more rapid than other types of promotional spending and its use is more evident within the lay press.

The potential ramifications of DTC advertising are not all bad. DTC advertising helps to meet a growing consumer demand for information. While the attitudes of health care professionals toward DTC advertisements have not been very positive, consumers are overwhelmingly supportive. Nearly half of the respondents to one survey who had seen or heard a prescription drug advertisement agreed that such advertisements help them make better decisions about their health, and more than 60% who had seen a physician during the previous 3 months believed that the advertisements helped them to have better discussions with their doctors concerning their health.[3] Many consumers taking a medication who witnessed an advertisement for it reported feeling better about the product's safety.[3] Indeed, it appears as though consumers desire the risk information presented within the major statement of televised DTC advertisements.[23]

Perhaps more importantly, DTC advertisements may alert consumers to treatment options for conditions that they previously thought were untreatable or for which previous modalities of treatment were contraindicated.[12] DTC advertising has helped introduce consumers to nonsedating antihistamines, antihyperglycemic agents, antihyperlipidemic agents, selective cox2-inhibitors, protein-pump inhibitors and other therapies. The Center for Drug Evaluation and Research (CDER) of the FDA delineated 5 clinical situations in which DTC advertising may contribute to increased drug usage[12]:

- Category A: New therapies intended to treat conditions that were formerly untreatable or only marginally treatable;
- Category B: Drugs for conditions that have a history of being underdiagnosed and undertreated even though therapies are available;
- Category C: Drugs whose lower risks or milder side effects expand the number of patients who can tolerate them;
- Category D: Branded products that have cheaper, generic or OTC equivalents;
- Category E: Products that provide little benefit, but that physicians may prescribe anyway, either out of ignorance or to accommodate patients.

The CDER believes that DTC advertising serves the public's interests in 3 of these situations (Categories A, B, and C).

By alerting patients to various conditions and treatment modalities, DTC advertisements may spur them to consult their primary care providers more frequently. This could result in earlier detection of the condition the drug is used to treat and perhaps detection of other unrelated health problems during the physician's examination. Thus, DTC advertising has the potential to improve health outcomes.

While opponents of DTC advertising express concern over its effect on patient-provider communication, DTC advertising may spur patients to initiate dialog with providers, which could facilitate a more effective dyadic exchange.[4,24] Such open communication could actually improve rather than hinder these relationships. One consequence of effective communication may be better adherence to medical recommendations, since adherence is higher among patients who are satisfied with their care and whose preferences are considered when the therapeutic selection is made.[4,25]

Improved outcomes and self-efficacy in treatment decisions may actually result in decreased overall health care costs in the long run, even while prescription drug costs continue to rise. Additionally, one study demonstrated that while the types of drugs being advertised are more than likely to be newer, more expensive therapies, the rate of inflation for drugs promoted directly to consumers did not exceed the price inflation associated with other drugs.[26] DTC advertising costs are not passed on directly to consumers any more than are other types of marketing costs.

Finally, other types of promotional efforts by drug manufacturers have come under increased scrutiny. A growing number of observers believe that promotional activities geared toward physicians have become too heavy-handed.[4] Under the auspice of "detailing," pharmaceutical sales representatives tender gifts such as free meals and travel directly to prescribers. The impact of such practices may be at least as deleterious on prescribing patterns as DTC advertising. The possible ramifications of DTC advertising, both good and bad, are largely just that—possibilities. Its long-term effects remain unknown.

Opportunities and Challenges Afforded by DTC Advertising

While pharmacists are entitled to their opinions of DTC advertising, the public is best served by dealing proactively with this phenomenon, rather than opining its virtues or detriments. Pharmacists have a responsibility to serve as patient advocates and providers of information. Pharmacists can build relationships with patients by taking the opportunity to answer their questions about drugs they have seen advertised. The results can be good for both the patient and for business. Following are a few suggestions for effective pharmacy practice in an era of DTC advertising:

- Maintain active reading habits. Keep up with readings in professional journals. You will be alerted of newly marketed drug products and may possibly be made aware of upcoming DTC advertisement campaigns. This will enable you to be more prepared when patients approach you with specific questions. Additionally, while it may not be possible to read every magazine and watch every television show, it is a good idea to take an inventory of the more popular DTC advertisements being disseminated.
- Request information about upcoming DTC advertising campaigns from pharmaceutical sales representatives. This will help you stay informed. If the representative is unable or unwilling to provide such information, contact a district or regional manager.
- Be informed and prepared to answer questions about products advertised. Do not jeopardize relationships with your patients by appearing to be unwilling to talk with them about the drugs advertised or about their disease states. Instill their confidence in you by being genuinely enthused about talking with them.
- Resist the temptation to be negative. If it appears as though a particular advertisement is misleading patients, remember that the patient is not to blame.
- Do not underestimate the patient's knowledge. While patients do not have your knowledge of therapeutics, they may have done a considerable amount of research about a drug product and the conditions it is used to treat before approaching you. You will only cast yourself in a negative light if you confront them with a condescending attitude.
- Provide unbiased information. The queries you receive from patients may sometimes be for drugs that are appropriate for them and sometimes for drugs that are not. All queries, however, should result in a healthy dialog between the two of you. Be objective and do not base your information on whether you support the advertisement or the product's manufacturer.
- Provide information on indications and risks. Some DTC advertisements hurriedly present risk information and present the drug's indications in a manner that may confuse patients.
- Provide information on directions for use. More and more patients will be obtaining prescriptions for drugs they specifically requested from their physician, without you necessarily knowing it. Perhaps somewhat taken for granted is information on how to take the product safely.
- Educate patients at every opportunity. For example, tell them in layperson's terms why the newer antihistamines are less sedative or why cox2-inhibitors are less likely to cause gastrointestinal side effects and need only be taken once daily. You may be surprised at how much they enjoy these little lessons and keep coming back for more.
- Be aware that a patient making an inquiry about a drug may contemplate procuring it from a specious Internet source. While legitimate pharmacy operations exist on the Web, there are also illegitimate ones. Some patients may inquire about the effectiveness of a drug because they are planning to obtain it from an Internet source without first seeing a licensed physician. When patients make inquiries about a drug, remind them that they should first discuss with their doctor whether the drug is appropriate for them.
- Inform sales representatives and the FDA of misleading information in DTC advertisements. If you discover that a particular advertisement may be misleading patients about the drug or the condition it treats, be proactive. If the problem appears particularly serious, contact the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the FDA's Center for Drug Evaluation and Research. They can be reached by telephone (301–827–2828), fax (301–827–2831), or on the Web at fda.gov/cder/ddmac.
- Urge your patients to contact DDMAC, too. It may be best that DDMAC hears this not only from you, but directly from the patient.
- Use the Web to your advantage. For those in an ownership position, consider using the Web to

offer an "ask the pharmacist" service. Welcome questions from patients.

- Advertise your consultative services. This is additional advice for managers/owners. Consider a sign reading something like this: "We welcome questions about drugs you have read about or seen advertised on TV or magazines." It will prove beneficial to your patients and perhaps to the pharmacy's bottom line.

ASSESSMENT

The instructor placed 5 questions pertaining to DTC advertising on the students' final examination. The average number correctly answered by students was 4.04 (80.8%) on an examination on which students averaged approximately 79.6%. There was no other assessment of knowledge pertaining to DTC advertising.

The PHBAS 410 course has been very well received by students, as evidenced from both University TEQ scores (overall 4.51 on a scale ranging from "1" to "5") and School curricular survey data (104 of 105 students completing the survey indicated that "course objectives were adequately met"). Students have provided written feedback on the TEQ indicating their satisfaction with the "special topics" lectures and with this one on DTC advertising, in particular. One student indicated that they will "look at those drug advertisements with a closer eye," while another commented, "I never realized those advertisements had so many implications." Another simply added, "I really enjoyed the class on advertising. It was very different than the usual kind of things we get in pharmacy school."

Some students have expressed the opinion verbally to the instructor and on curricular surveys that the course be taught earlier in the curriculum (third year, overall, or first year in the professional phase) as this course helps them to "make sense of things at work" and "understand what's going on in the world."

The course's enrollment, ranging from 106 to 145 students during the past 4 offerings, and a prior lack of teaching assistants has limited the number of active-learning strategies used in PHBAS 410. With recently acquired teaching assistants, the revised course will afford students the opportunity to evaluate print and televised DTC prescription drug advertisements and be tested using a short answer and essay format. A recitation may be added to the course allowing, among other things, students to evaluate the literature discussing the impact of DTC advertising.

SUMMARY

DTC advertising is an important tool in today's marketing mix among manufacturers of brand-name drugs. While DTC advertising has had an impact on practitioner and consumer/patient attitudes, its long-term effects on health outcomes and costs have yet to be determined. Professional pharmacy degree students should be instructed to view DTC advertising objectively and take advantages of the opportunities it presents to open dialog with patients and promote the public's health.

REFERENCES

1. Hall SS. The Claritin effect. Why drugs cost so much: A case study. *New York Times* Magazine. March 11, 2001:40-45;59;91-2;100.
2. Bradley LR, Zito JM. Direct-to-consumer prescription drug advertising. *Med Care*. 1997;35:86-92.
3. Lyles A. Direct marketing of pharmaceuticals to consumers. *Ann Rev Public Health*. 2002; 23:73-91.
4. Findlay SD. Direct-to-consumer promotion of prescription drugs: Economic implications for patients, payers and providers. *Pharmacoeconomics*. 2001;19:109-19.
5. Frank R, Berndt ER, Donohue J, Epstein A, Rosenthal M. Trends in direct-to-consumer advertising of prescription drugs. Kaiser Family Foundation. Available at: http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14881. Accessed March 07, 2002.
6. Sheffet MJ, Kopp SW. Advertising prescription drugs to the public: headache or relief? *J Public Policy Market*. 1990;9:42-61.
7. Halm EA, Causino N, Blumenthal D. Is gatekeeping better than traditional care? A survey of physicians' attitudes. *JAMA*. 1997;278:1677-81.
8. Biddle, AK, DeVellis RF, Henderson G, Fasick SB, Danis M. The health insurance puzzle: a new approach to assessing patient coverage preferences. *J Community Health*. 1998;23:181-194.
9. Haug MR, Lavin B. *Consumerism in Medicine: Challenging Physician Authority*. Beverly Hills, CA: Sage; 1983:183.
10. Adamcik, B.A. The consumers of health care. In: Fincham JE, Wertheimer AI, eds. Pharmacy and the U.S. Healthcare System. Binghamton, NY: Haworth; 1991:325-96.
11. Greene J. Al wants more hair, less fat, and a better sex life . . . and he wants his health plan to pay for it. *Hosp Health Networks*. 1999;73:36-40;42.
12. Hunt M. National Health Policy Forum. Direct-to-consumer advertising of prescription drugs. Washington, D.C., The George Washington University; 1998.
13. Morris LA, Brinberg D, Klimberg R, Rivera C, Millstein LG. The attitudes of consumers toward direct advertising of prescription drugs. *Public Health Rep*. 1986;101:82-9.
14. Morris LA, Millstein, LG. Drug advertising to consumers: Effects of formats for magazine and television advertisements. *Food Drug Cosm Law J*. 1984; 39:497-503.
15. Federal Register. 56 (September 9, 1985):36677.
16. Lipsky MS, Taylor CA. The opinions and experiences of family physicians regarding direct-to-consumer advertising. *J Fam Pract*. 1997;45:495-9.
17. Sullivan DL, Schommer JC, and Birdwell SW. Consumer retention of risk information from direct-to-consumer advertising. *Drug Inf J*. 1999;33:281-9.
18. T'Hoen E. Direct-to-consumer advertising: for better profits or for better health? *Am J Health-Syst Pharmacy*. 1998;55:594-7.
19. Christensen TP, Ascione FJ, Bagozzi RP. Understanding how elderly patients process drug information: a test of information pro-

cessing. *Pharm Res*. 1997;14:1589-96.
20. Hoog S. Over-the-counter drug advertising: argumentation or persuasion. *J Pharm Market Manage*. 1994;9:69-91.
21. Shah M, Holmes ER, Desselle SP. The use of persuasion in DTC advertisements of prescription drugs: a content analysis of leading consumer magazines from 1995-2000. *J Pharm Market Manage*. 2003;15:in press.
22. Woloshin S, Schwartz LM, Tremmel J, Welch HG. Direct-to-consumer advertisements for prescription drugs: what are Americans being sold? *Lancet*. 2000;358:1141-6.
23. Sullivan D. Evaluating information in consumer advertisements of prescription drugs. *Ann Pharmacother*. 2001;35:1494.
24. Roth MS. Patterns in direct-to-consumer prescription drug print advertising and their public policy implications. *J Pub Policy Market*. 1986;15:63-75.
25. Pizzi LT, Bikupiak JE. Patient compliance and its impact on treatment outcomes. *Disease Manage Health Outcomes*. 1999;6:269-78.
26. Kopp SW. Direct-to-consumer advertising and consumer prescription prices. *Drug Inf J*. 1996;30:59-65.