9.6.7 Direct-to-Consumer Advertisements of Prescription Drugs

Direct-to-consumer advertising may raise awareness about diseases and treatment and may help inform patients about the availability of new diagnostic tests, drugs, treatments, and devices. However, direct-to-consumer advertising also carries the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patients' health and safety, and compromising patient physician relationships.

In the context of direct-to-consumer advertising of prescription drugs, physicians individually should:

(a) Remain objective about advertised tests, drugs, treatments, and devices, avoiding bias for or against advertised products.

(b) Engage in dialogue with patients who request tests, drugs, treatments, or devices they have seen advertised to:

(i) assess and enhance the patient's understanding of the test, drug or device;

(ii) educate patients about why an advertised test, drug, or device may not be suitable for them, including providing cost-effectiveness information about different options.

(c) Resist commercially induced pressure to prescribe tests, drugs, or devices that may not be indicated.

(d) Obtain informed consent before prescribing an advertised test, drug, or device, in keeping with professional standards.

(e) Deny requests for an inappropriate test, drug, or device.

(f) Consider reporting to the sponsoring manufacturer or appropriate authorities direct-to-consumer advertising that:

(i) promotes false expectations;

(ii) does not enhance consumer education;

(iii) conveys unclear, inaccurate, or misleading health education messages; (iv) fails to refer patients to their physicians for additional information; (v) does not identify the target population at risk;

(vi) encourages consumer self-diagnosis and treatment.

Collectively, physicians should:

(g) Encourage and engage in studies that examine the impact of direct-to-consumer advertising on patient health and medical care.

(h) Whenever possible, assist authorities to enforce existing law by reporting advertisements that do not:

(i) provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition;

(ii) clearly explain warnings, precautions, and potential adverse reactions associated with the drug product;

(iii) present summary information in language that can be understood by the consumer

(iv) comply with applicable regulations;

(v) provide collateral materials to educate both physicians and consumers.

AMA Principles of Medical Ethics: II, III

Background report(s):

CEJA 3-A-Report Modernized *Code of Medical Ethics*

CEJA 4-I-98 Direct to consumer advertising of prescription drugs

9.6.7 Direct-to-Consumer Advertisements of Prescription Drugs

Direct-to-consumer advertising may raise awareness about diseases and treatment and may help inform patients about the availability of new diagnostic tests, drugs, treatments, and devices. *However, direct-to-consumer advertising also carries the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patients' health and safety, and compromising patient physician relationships.* [*new language sets out key ethical values and concerns explicitly*]

In the context of direct-to-consumer advertising of prescription drugs, physicians individually should:

(a) Remain objective about advertised tests, drugs, treatments, and devices, avoiding bias for or against advertised products. [*new guidance addresses gap in current opinion*]

(b) Engage in dialogue with patients who request tests, drugs, treatments, or devices they have seen advertised to:

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(ii) educate patients about why an advertised test, drug, or device may not be suitable for them, including providing cost-effectiveness information about different options.

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AMA Principles of Medical Ethics: II, III

4. DIRECT-TO-CONSUMER ADVERTISEMENTS OF PRESCRIPTION DRUGS

HOUSE ACTION: RECOMMNEDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED:

INTRODUCTION

In August 1997, the Food and Drug Administration (FDA) issued a draft guidance that clarifies the restrictions on broadcast prescription drug advertisements [hereinafter "Draft Guidance"]. The purpose of the Draft Guidance is to describe an approach as to how sponsors can meet certain existing FDA regulatory requirements for advertising prescription drugs on radio and television. The changes proposed in the Draft Guidance, discussed in detail below, help promote the already growing extent to which pharmaceutical industries advertise prescription drugs directly to the public.

A chief goal of any business is to make a profit. The foremost goal of medicine is to promote the health of patients and the public. For this reason, there has been considerable attention paid by the medical profession to how and under what circumstances a medical professional may interact with a business. Gift giving and educational sponsorship guidelines are examples of this oversight.

In this report, the Council on Ethical and Judicial Affairs addresses the potential strengths and pitfalls of direct-to-consumer advertising of prescription drugs and offers guidance to physicians when these activities affect their practices.

REGULATION OF DIRECT-TO-CONSUMER ADVERTISEMENTS

Under the Federal Food, Drug, and Cosmetic Act (the Act), the FDA regulates direct-to-consumer advertising of prescription drugs in the same way they regulate advertisements directed to professionals. Foremost, no advertisement may be false or misleading. To comply with these regulations, direct-to-consumer advertisements may make only claims that are supported by scientific evidence and that are consistent with FDA-approved patient labeling. For prescription drugs, the Act requires advertisements to contain "information in brief summary relating to side effects, contraindications, and effectiveness." This information is usually disclosed in a statement called the "brief summary."

Prior to August 1997, all advertisements naming a product together with the condition for which it may be used had to provide this "brief summary" in connection with the broadcast advertisement. For this reason, most advertisements that named ailments occurred in printed media. Television advertisements simply could not afford the time and money it would take to set out all the needed information. The Draft Guidance issued in August 1997 allows sponsors of broadcast advertisements to present a brief summary or, alternatively, an "adequate provision...for dissemination of the approved or permitted package labeling in connection with the broadcast presentation." This alternative requirement is referred to as the "adequate provision" requirement and can be met by providing a mechanism to obtain package labeling, such as an operating toll-free telephone number or an Internet address. Use of an "adequate provision" does not replace the requirement that advertisements must provide a "major statement" which discloses the drug's major risks in either the audio or audio and visual parts of the advertisement. Thus, while the Draft Guidance allows pharmaceutical industries to proceed with broadcast advertisements that name a product and an ailment together, it does not relax any of the other advertising requirements.

In addition to concerns about print and broadcast advertisements, advertising via the Internet raises special concerns about the reliability of information. The Internet offers the pharmaceutical industries an extensive network through which they can advertise their products to the public. It is reported that more than 10,000 Internet websites are devoted to health and medical information. The FDA currently reviews Internet promotions

as it does other forms of promotion. However, other nations regulate advertising differently. Since the Internet transcends international borders, it is difficult to regulate direct-to-consumer advertisements consistently with each nation's laws.

ARGUMENTS AGAINST DIRECT-TO-CONSUMER ADVERTISEMENTS OF PRESCRIPTION DRUGS

The pharmaceutical industries argue that their intention in advertising directly to the public is to better educate consumers, thereby providing them the opportunity to promote healthier living. A fundamental assumption of this claim, however, is that the provided information is thorough, accurate and balanced. Direct-to-consumer advertisements are accompanied by two kinds of information: advertisement information from the sponsor and information required by the FDA. The former is not necessarily aimed at providing patients with comprehensive information, and the latter may not be presented in a way that promotes patient understanding. Despite the FDA's encouragement to sponsors to write nonpromotional information relating to side effects, contraindications and effectiveness in consumer-friendly language, package inserts or brief summaries may still be filled with medical jargon and presented in small print. This technique of delivering information does not ensure that the consumer understands the information or is able to make an informed choice about therapy.

Moreover, advertising material may not meet existing regulatory standards. One study of promotional materials handed out by drug sales people found that 42% failed to comply with one or more FDA regulations and 35% of the materials lacked fair balance between benefits and risks of drugs. Another study published in the Annals of Internal Medicine reviewed pharmaceutical advertisements appearing in leading medical journals. The reviewers' assessments of both accuracy of scientific material and compliance with FDA labeling standards revealed that in 44% of cases the advertisement would lead to improper prescribing. Thirty-two percent of the advertisements were judged as having headlines that mislead the reader about efficacy and 57% of advertisements were considered by the reviewers to have little or no educational value.

It is not surprising that these surveys and statistics are controversial since direct-to-consumer advertising has become an increasingly lucrative and popular practice. A recent survey found that direct-to-consumer advertising had increased 42% between 1996 and 1997. Since the August 1997 proposed relaxation of FDA guidelines, spending in the United States on direct-to-consumer advertisements has exceeded that on beer advertisements. During that same time period, patient requests for brand-name drugs increased 59%. This situation is complicated by the fact that consumers tend to receive information from a variety of sources including TV, radio and print ads, the Internet, store displays, general media reference books, consumer reports, family members, and friends and colleagues. Physician advice may be among the last of these sources consulted.

Other arguments against direct-to-consumer advertising are based on safety and on the need to retain the therapeutic encounter within an environment of professional standards. The direct advertising model omits the important aspects of the patient's interacting with the professional. Physicians also claim that direct-to-consumer advertising strains the patient-physician relationship. Such advertising has generated a demand for certain products without the accompanying need. Physicians report feeling bombarded with misinformed requests for prescriptions and met with suspicion and hostility when they deny the request.

ARGUMENTS IN FAVOR OF DIRECT-TO-CONSUMER ADVERTISEMENTS OF PRESCRIPTION DRUGS

Physicians recognize that there is some merit in direct-to-consumer advertising if it serves as an effective medium for providing health information to consumers. Patients informed about therapeutic possibilities are in a better position to participate in their own care. Advertising may also alert patients to new treatments available, a benefit to those who rarely come in contact with physicians or health care organizations. These activities may increase patient responsibility for pursuing healthy lifestyles. Some consider direct-to-consumer advertising to be consistent with efforts to promote patients' access to useful information. For example, the extent of Internet use

suggests that there is high consumer interest in information regarding prescription drugs. In 1997, approximately 1.5 million people visited an Internet site that lists the top 200 prescription drugs.

It has been argued that physicians are making unauthorized proxy decisions by denying consumers the information offered by direct-to-consumer advertising. Those in favor of direct-to-consumer advertising push for a reduction in this sort of perceived physician paternalism. After all, while the advertisements provide information to the public about prescription drugs, the physician still acts as the gatekeeper. This level of professional input should be sufficient to ensure that patients are not being misinformed and are making educated decisions. Direct-to-consumer advertising, in this regard, promotes communication between physicians and patients. Physicians may use patients' queries about advertised prescription drugs as opportunities to increase their understanding of patients' needs and fears and to initiate a process of educating patients about their health.

PROFESSIONAL INVOLVEMENT IN DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS

In the coming information age, the proper provision and use of information will be more important than ever. This requires professional involvement and initiative. For example, in 1993 the American Medical Association (AMA), in consultation with the FDA, developed "Guidelines for Direct-to-Consumer Prescription Drug Advertising" for AMA consumer media. Based on these guidelines, product-specific advertisements would satisfy certain criteria intended to best serve patients' health, safety and pocketbooks. The guidelines include criteria such as, "The ad will convey a clear, accurate and responsible health education message" and "In all cases, the ad should refer patients to their physicians for more information."

It may be unrealistic to expect the FDA to monitor all advertisements and police those advertisers who are violating the requirements. Therefore, some control must come from professional standards and activities. Medical professionals must be committed to reporting to the FDA advertisements that do not meet FDA advertising standards. Moreover, medical professionals should report incidences when patients appear to be misled or misinformed from a particular advertisement by inappropriately requesting a drug. Without feedback from physicians who encounter patients on a clinical basis, the FDA has little information about the harms or benefits of direct-to-consumer advertising of prescription drugs. It is too soon to tell how direct-to-consumer advertising will affect patient health care. Physicians should both encourage and become involved in studies regarding the effect of direct-to-consumer advertisements on health care. Such studies should examine whether direct-to-consumer advertising improves the communication of health information, enhances the patient-physician relationship, and contains accurate and reasonable information on risks, precautions, adverse reactions and costs.

Physicians may have a responsibility to challenge any practice that places patients' health care in jeopardy. It would be impractical, and arguably inappropriate, to prevent patients and consumers from viewing such advertisements and in turn making requests from their physicians based on what they have seen. Instead, physicians should be prepared to respond to the impact of direct-to-consumer advertising of prescription drugs when it affects their clinical practice. Physicians must maintain professional standards of informed consent and ensure that discussion occurs between patients and physicians.

All physicians should make a concerted effort to respond to their patients' concerns. For example, when a patient comes to a physician with a request for a drug he or she has seen advertised, the physician and the patient should engage in a dialogue that would assess and enhance the patient's understanding of what the treatment entails. This would confirm that the patient was indeed properly informed and has given informed consent. In keeping with sound medical decision-making, physicians should make available to patients those drugs that would offer benefits to the patient. However, while physicians should not be biased against drugs that are advertised, physicians should resist commercial pressure to prescribe such drugs when not indicated. This may involve denying requests for inappropriate prescriptions, educating the patient as to why certain advertised drugs are not suitable treatment options, and include, when appropriate, information on the cost effectiveness of prescription drug options.

According to AMA statements, physicians should be concerned about advertisements that do not enhance consumer education; do not convey a clear, accurate and responsible health education message; do not refer patients to their physicians for more information; and do not identify the target population at risk and discourage the consumers' self-diagnosis and self-treatment. Physicians may chose to report these concerns directly to the pharmaceutical company that sponsored the advertisement. Such efforts may provoke changes in the sponsor's advertising strategy. Also, to assist the FDA in enforcing existing law and tracking the effects of direct-to-consumer advertising, physicians should, whenever reasonably possible, report to them advertisements that do not meet the criteria listed below.

CONCLUSION

Direct-to-consumer advertising of prescription drugs in both print and broadcast media is now common. While there is legitimate opposition to this form of information delivery, there is also reason to believe that patients' health and medical care may benefit. Several appropriate steps have already been taken to ensure that proper advertising guidelines are in place. However, the profession needs to take an active role in ensuring that such guidelines are enforced and that the care their patients receive is not compromised as a result of the impact of direct-to-consumer advertising on clinical practice.

RECOMMENDATIONS

While the American Medical Association continues to be concerned about the acceptability of direct-to-consumer advertising, the Council on Ethical and Judicial Affairs recognizes the growth of this practice and the accompanying need for guidance in this arena. The Council on Ethical and Judicial Affairs therefore recommends that the following statements be adopted and that the remainder of this report be filed:

1. The FDA has a critical role in determining future directions of direct-to-consumer advertising of prescription drugs and in determining how the public and profession are informed about such health care products. Physicians should work to ensure that the FDA remains committed to advertising standards that protect patients' health and safety.

2. Physicians should encourage studies regarding the effect of direct-to-consumer adverting on patient health and medical care. Such studies should examine whether direct-to-consumer advertising improves the communication of health information; enhances the patient-physician relationship; and contains accurate and reasonable information on risks, precautions, adverse reactions and costs. Physicians should be involved in the studies to ensure that they are conducted accurately.

3. When prescribing drugs, physicians must maintain professional standards of informed consent. When a patient comes to a physician with a request for a drug he or she has seen advertised, the physician and the patient should engage in a dialogue that would assess and enhance the patient's understanding of what the treatment entails. Although physicians should not be biased against drugs that are advertised, physicians should resist commercially induced pressure to prescribe such drugs when not indicated. Physicians should deny requests for inappropriate prescriptions, educate patients as to why certain advertised drugs may not be suitable treatment options, and include, when appropriate, information on the cost effectiveness of prescription drug options.

4. Physicians must remain vigilant to assure that direct-to-consumer advertising does not promote false expectations. According to AMA statements, physicians should be concerned about advertisements that do not enhance consumer education; do not convey a clear, accurate and responsible health education message; do not refer patients to their physicians for more information; and do not identify the target population at risk and discourage the consumers' self-diagnosis and self-treatment. Physicians may choose to report these concerns directly to the pharmaceutical company that sponsored the advertisement. To assist the FDA in enforcing existing law and tracking the effects of direct-to-consumer advertising, physicians should, whenever reasonably possible, report to them advertisements that:

   a. do not provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition;

   b. do not clearly explain warnings, precautions, and potential adverse reactions associated with the drug product;

   c. do not present summary information in language that can be understood by the consumer;

   d. do not comply with applicable FDA rules, regulations, policies and guidelines as provided by the FDA; or

   e. do not provide collateral materials to educate both physicians and consumer.

(References for this report can be obtained from the Ethics Standards Division.)

5. ETHICAL CONSIDERATIONS OF FEES FOR REFERRALS

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

Resolution 201, adopted at the 1998 Annual Meeting, asked the Council on Ethical and Judicial Affairs (CEJA) to study:

"the ethical and legal implications of paying a fee in order to receive patient referrals".

ETHICAL CONSIDERATIONS OF FEES FOR REFERRALS

CEJA has previously stated in Opinion 6.02, "Fee Splitting":

Payment by or to a physician solely for the referral of a patient is fee splitting and is unethical.

A physician may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source.

In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the physician on matters of referral. All referrals and prescriptions must be based on the skill and quality of the physician to whom the patient has been referred or the quality and efficacy of the drug or product prescribed.