STATEMENT

of the

American Medical Association

to the
Special Committee on Aging
United States Senate

Presented by Nancy H. Nielsen, MD, PhD
Speaker, House of Delegates
American Medical Association

RE: DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS: EXPLORING THE CONSEQUENCES

July 22, 2003

Mr. Chairman and members of the Committee, good morning. My name is Dr. Nancy H. Nielsen. I am an internist from Buffalo, New York, and the Speaker of the American Medical Association (AMA) House of Delegates. On behalf of the physician and medical student members of the AMA, I am honored to have been invited to discuss with the Committee the AMA's perspective on the role of direct-to-consumer advertising (DTCA) in health care, including its impact on the physician-patient relationship, its role as a source of information for patients, and its other potential benefits and disadvantages.

Introduction

Direct-to-consumer advertising has become widespread in recent years and is well known to most American households. Anyone who watches a commercial television program or reads

newspapers or magazines cannot help but notice the dramatic increase in the number of prescription drug ads. According to a recent report by the Kaiser Family Foundation, consumer surveys indicate that the percentage of people who report they have seen an advertisement for a prescription drug on television or heard one on the radio more than doubled between 1993 and 2000, hitting 81% by 2002.[1] Many physicians report that their patients have asked them about drugs as a direct consequence of DTCA, and some estimates indicate that as many as 25% of Americans have asked their physicians about a drug as a result of seeing an advertisement.[2]

The growth in spending on DTCA between 1989 and 2001 has been truly phenomenal: in 1989, the pharmaceutical industry spent only $12 million on DTCA, compared to $2.7 billion in 2001.[3] Since 1994, total spending on DTCA has grown nearly tenfold.[4] Pharmaceutical companies have increased spending on DTCA faster than they have increased spending on research and development. Between 1997 and 2001, spending on DTCA increased 145 percent, while research and development spending increased only 59 percent.[5] Over 70% of DTCA in 2001 was spent on TV ads.[6]

While common and legal, product-specific advertising of prescription drugs directly to consumers remains controversial in the health care arena generally and among AMA's member physicians specifically. Proponents argue that DTCA provides another mechanism to educate consumers about health conditions and possible treatments, which makes them more informed consumers and enables them to take a more active role in their health care. They also believe that after viewing or reading an advertisement for a prescription drug,

patients will seek out their physicians and have a more knowledgeable discussion about their health condition, and if applicable, possible treatment options.

Opponents of DTCA, including many physicians, argue that DTC advertisements are simply promotional marketing and lack educational value, and may mislead consumers into believing that they need the advertised medication. This, in turn, may adversely affect the physician-patient relationship, lead to inappropriate prescribing, increase utilization and health care costs and potentially, result in adverse health outcomes.

The AMA has been, and continues to be, concerned about the possible negative impact of DTCA on the physician-patient relationship and its impact on the already spiraling increase in prescription drug costs. The latter concern is particularly relevant now, as Congressional negotiators are debating the details of adding a prescription drug benefit to the Medicare program. The AMA is also concerned about the need to adequately fund the Food and Drug Administration (FDA) so that it can carry out its enforcement role over DTCA, as well as provide funding for quality, independent research on the impact of DTCA. These concerns are discussed in more detail later in this testimony.

History of DTCA and AMA Policy

Prescription drug advertising in the United States historically was focused mainly on physicians, who were the sole decision-makers in terms of choosing prescription drugs. In the early 1980s, as patients became more involved in their treatment, the pharmaceutical industry began marketing prescription drugs directly to consumers. Many, including the AMA, were

vigorously opposed to this, primarily on the grounds that these products were complex, not without risk, and required a prescription in order to be dispensed.

The FDA imposed a moratorium on DTCA in 1983, then lifted it in 1985, after concluding that it lacked the legal grounds to prevent this form of advertising. FDA mandated that DTC advertisements must meet the same requirements as prescription drug advertising for health professionals. Thus, DTC ads must not be false or misleading, must present a fair balance between effectiveness and risk information, and must reveal material facts, i.e., list all risk concepts in the form of a so-called "brief summary."

Until 1992, the AMA remained opposed to product-specific DTCA. However, as such advertising gradually became more common in print media, primarily magazines, the AMA reassessed its position. In 1992, the AMA's House of Delegates (our policy-making body) adopted a new position that allowed the AMA, on a case-by-case basis, to accept disease-specific, health education consumer advertisements, which may include mention of brand-name prescription drugs. In 1993, with input from the FDA, the AMA developed guidelines for an acceptable DTC advertisement.

Perhaps the most significant event in recent years regarding DTCA was the FDA's publication of a "draft" Guidance in 1997 which proposed to relax the requirement for presenting all of the risk information, i.e., the brief summary, in all broadcast advertisements – the primary focus being on television ads. The FDA stated that the so-called "adequate provision" could be met if the advertisement listed major risk information and provided four

referrals for full prescribing information – (1) see your doctor or pharmacist; (2) a 1-800 number for the pharmaceutical company; (3) an Internet address for the company; and (4) a reference to a print advertisement for the product. As a result, both the extent and frequency of advertisements for prescription drugs significantly increased in both print and broadcast media.

In 1997, the AMA sent a letter to the FDA expressing its concerns about the potential adverse impact that expanded DTCA might have on the physician-patient relationship and the potential for negative public health and economic outcomes. The AMA asked the FDA to survey physicians on the impact of DTCA on their practices and to do an economic analysis of the impact of widespread DTCA. The FDA, however, published a final guidance on DTCA in broadcast media in 1999 that was essentially the same as the draft guidance, without doing a physician survey or economic analysis.

While the AMA continued to be concerned about DTCA, our House of Delegates decided that a proactive approach needed to be taken. In 1998, the AMA's Council on Ethical and Judicial Affairs (CEJA) developed an ethical opinion (E-5.015) to help our profession and individual physicians deal responsibly with DTCA for the best interests of their patients. Then, in 1999 the AMA House of Delegates adopted as policy a series of recommendations from an AMA Board of Trustees report on DTCA. The AMA's intent was both to help define what are satisfactory DTC advertisements and to advocate for the necessary research to assess the impact of DTCA on the patient-physician relationship as well as on health and economic outcomes. This policy (H-105.988) was modified slightly in December of 1999, reaffirmed in

June 2000, and again slightly modified in December of 2000 and June of 2001. The policy continues to be revisited and modified as circumstances warrant.

Current AMA Policy on DTCA

Under AMA policy, only those product-specific DTC advertisements that follow the guidelines that were developed by the AMA, in consultation with the FDA in 1993, are acceptable. AMA policy includes the following guidelines:

a) The advertisement should be disease-specific and enhance consumer education;
b) The ad should convey a clear, accurate and responsible health education message (i.e., information on the prevention or treatment of a disease, disorder, or condition);
c) In all cases, the ad should refer patients to their physicians for more information;
d) The ad should not encourage self-diagnosis and self-treatment, but should identify the consumer population at risk;
e) Discussion of the use of the drug product for the disease, disorder, or condition should exhibit fair balance;
f) Warnings, precautions, and potential adverse reactions associated with the drug product should be clearly explained so as to facilitate communication between physician and patient;
g) No comparative claims can be made for the product. In the interest of fair balance, alternative non-drug management options for the disease, disorder, or condition can be included;

h) The brief summary information should be presented in language that can be understood by the consumer;

i) The advertisement must comply with applicable FDA rules, regulations, policies and guidelines as provided by their Division of Drug Marketing, Advertising and Communications; and

j) The ad should be part of a manufacturer's education program that would include collateral materials to educate both physician and consumer.

AMA policy has seven other points:

1. Our AMA opposes product-specific DTC advertisements, regardless of medium, that do not follow the above AMA guidelines.
2. Our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical industry to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.
3. Our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content, an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.
4. Our AMA encourages physicians to be familiar with the above AMA guidelines for product-specific DTCA and with the Council on Ethical and Judicial Affairs (CEJA) Ethical Opinion E-5.015 and to adhere to the ethical guidance provided in that Opinion.

5. Our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical industry to make policy changes regarding DTCA, as necessary.
6. Our AMA advocates that DTC drug advertisements contain a disclaimer "Your physician may recommend other, appropriate treatments."
7. Our AMA supports an appropriate level of funding for the FDA to more closely review DTCA of prescription drugs through television, radio, print, and other new forms of media, such as the Internet.

AMA's current policy recognizes that DTCA is legal and widespread, and most likely, here to stay. While the AMA's guidelines for an acceptable DTC ad generally have been well-received by both the FDA and the Pharmaceutical Research and Manufacturers of America (PhRMA), regrettably neither entity has endorsed them.

Key AMA Concerns about DTCA

As noted earlier, the debate over DTCA continues within the broader health care community generally and within the AMA specifically. Continuing concerns about DTCA within the physician community, include: 1) whether DTC ads provide educational value, are fairly balanced, and adequately disclose risks to consumers; 2) what is the impact of such ads on physician-patient relationships; and 3) what is the impact of such ads on health care utilization

and costs. Each of these concerns is addressed below.

1. Is DTCA Educational and Balanced?

One of the main tenets of the AMA guidelines is that DTCA should be educational, and not misleading. Do most product-specific ads meet the AMA's standard for educational value? This is difficult to answer, since what is educational to one individual may not be to another. While good data is hard to find on this issue, the majority of physicians most likely would not agree that the ads are educational. In one study that was published in the December 2000 issue of the *Journal of Family Practice*, the researchers reviewed over 300 print ads for 101 prescription drug products in 18 popular magazines over the previous decade. They found that while the advertisements were informative, they lacked important educational information about both the condition and the treatment for which the drug was being promoted.[7]

Although increased access by patients to accurate, objective information about tests to diagnose and drugs to treat illnesses is certainly important, there is the risk of confusion when commercially-driven promotional information is presented as educational. The issue is not whether consumers should obtain more information about treatment options – the real question is whether drug advertising, with its aim of selling a product, can provide the type of information consumers need or should have. Advertising has been described by one economist as "the science of arresting the human intelligence long enough to get money from it."[8] One executive of an advertising agency that focuses on DTCA has noted that "consumers react emotionally, so you want to know how they feel about your message and

what emotional triggers will get them to act…We want to identify the emotions that we can tap into to get that customer to take the desired course of action."[9]

In addition to assessing the educational value of DTCA, the AMA is concerned that consumers may not always get a balanced view of the benefits and risks of a product based on advertising. The FDA has made efforts to guide manufacturers to provide consumers with summary information, based on the drug's labeling, that is more useful and easily understood. For the most part, the AMA would concur that fair balance and adequate disclosure of risks appear in print advertisements, which require the "brief summary" (fine print) to be included. For television advertisements, however, it is more difficult to measure fair balance. Some of the ads are very effective at using pleasing, not to mention distracting, visuals as the major risk information is being discussed in audio only. Showing the major risks on screen as they are being discussed might improve fair balance.

Studies also have shown that patients have potentially dangerous misperceptions about DTCA. One research study suggested that one-half of consumers incorrectly believed that DTC advertisements are pre-approved by the FDA, and 43% incorrectly believed that only completely safe drugs can be advertised directly.[10] Another study found that consumers rated the safety and appeal of drugs described with an incomplete statement of risks more positively than similar drugs described with a more complete statement of risks.[11] These perceptions raise the question of whether widespread DTCA is giving consumers a false sense of security that prescription drugs are risk-free.

2. Impact of DTCA on Physician-patient Relationship

The AMA remains concerned about the impact of DTCA on the physician-patient relationship and the paucity of quality, independent peer-reviewed research to measure this impact. The consumer surveys that have been conducted, such as those by the FDA, *Time*, the AARP, the National Consumers League and *Prevention* magazine, suggest that DTCA increases: (1) physician office visits; (2) new diagnoses; (3) informed discussion between physician and patient about conditions and treatments; and, (4) unfortunately in some cases, demand for a specific advertised drug product. In a 2002 report by the General Accounting Office (GAO), the authors examined a number of consumer surveys and concluded that the percentage of consumers who, in response to a DTC ad, requested and received a prescription from their physician for a drug they were not currently taking was generally about 5 percent. The GAO estimated that this meant that about 8.5 million consumers in 2000 received a prescription drug after viewing a DTC ad and asking their physician for the drug.[12]

Although DTCA might have the positive effect of increasing physician office visits, resulting in the diagnosis of previously undiagnosed conditions and in better communication between physician and patient, many physicians complain that patients, armed with the latest DTC advertisements, come into their offices demanding the physician prescribe the advertised drug for them. We live in a society that prefers instant gratification and, taking a pill can often seem much easier than changing one's lifestyle. There is a danger that DTCA may cultivate a belief among the public that there is a pill for every ill and lead to an overmedicated society. If a medication is not necessary or appropriate, the physician is put in the uncomfortable and awkward position of defending why this is the case. Less time is available to diagnose and

treat the patient if the patient has a fixation on a particular drug as a result of a commercial. This can add strain and potentially distrust to a relationship that should be completely open.

A survey of physicians by the FDA, strongly supported by the AMA and released in January 2003, concluded that most physicians view DTCA as one of many factors that affect their practice and their interactions with patients, both positively and in some respects, negatively. The FDA survey also found that physicians felt they had to provide additional information to patients beyond what patients retained from the DTC advertisement. About 75 percent of physicians believed that DTCA causes patients to think the drug works better than it did, and many physicians felt some pressure to prescribe something when patients mentioned DTC ads. The FDA survey also found that about eight percent of physicians felt very pressured to prescribe the specific brand name drug when asked about it.[13] Various surveys have shown that some physicians prescribe the requested drug. One would like to believe that objective treatment decisions were made in every case. However, the question needs to be raised as to whether clinical judgment is being compromised in some cases to preserve a positive relationship with the patient.

3. Impact of DTCA on Health Care Costs and Utilization

The AMA also is concerned about the impact of DTCA on health care costs and utilization. DTCA is targeted at an audience that often is not responsible for paying for the product because most prescriptions (at least non-Medicare, for now) are paid for, at least in part, by private or public insurance. Articles in the lay press suggest that third-party payers are seeing disproportionate increases in drug budgets for classes of heavily advertised drugs. The key

question is whether these increased costs for advertised drugs are reducing costs in other health care areas so that the net effect is more cost-effective health care. This also places the physician in a difficult situation. On the one hand, the payer expects the physician to be cost-conscious and not prescribe the most expensive drug, if not medically indicated. On the other hand, payers also grade physicians based on patient satisfaction. The physician faces pressure from the patient requesting an expensive advertised drug and pressure from the payer to prescribe comparable but less expensive alternatives.

Some recent studies have concluded that DTCA does, in fact, lead to increased spending on drugs. A new study by researchers at the Harvard School of Public Health, Massachusetts Institute of Technology, and Harvard Medical School for the Kaiser Family Foundation, released in June 2003, found that increases in DTCA have a significant impact on drug spending growth. The authors estimated that in 2000, 12 percent of drug spending growth was related to increased spending on DTCA, with each additional dollar spent on DTCA yielding an additional $4.20 in drug sales in that year.[14] The GAO report also concluded that DTCA appeared to increase prescription drug spending and utilization. The GAO found that drugs promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Moreover, the GAO found that most of the spending increase for heavily advertised drugs is the result of increased utilization rather than price increases.[15]

These studies may reflect an appropriate increase in spending on drug treatments that were previously underutilized. Alternatively, this also could reflect wasteful spending on

expensive advertised drugs for which less expensive alternatives, or no drug at all, will work just as well. A clear answer to this important question is definitely needed.

Recommendations

The AMA offers the following conclusions and recommendations to the Committee as it examines the consequences of DTCA:

1. The AMA believes there is room for improvement in the educational value of DTC ads without compromising a pharmaceutical company's desire to promote their product. In this regard, the AMA urges the pharmaceutical industry to use the AMA's guidelines for DTCA. Responsible DTCA that is accurate and educational to consumers, that balances benefits and risks, and that promotes good health outcomes can have a positive impact on health care.
2. The AMA believes that consumers must be better educated to understand the limitations of DTC advertisements. The AMA stands ready to work with the FDA and consumer groups in such an educational endeavor.
3. The AMA would like to see more independent research on DTCA and, particularly, on its impact on the patient-physician relationship and on health outcomes and costs. The results of this research must be published in reputable, peer-reviewed journals and be available in the public domain. The AMA believes that both the industry that runs the advertisements and the government have an obligation to fund this research.
4. The AMA supports the concept that when companies engage in DTCA, they should assume increased responsibility for the informational content, an increased duty to

warn consumers, and possible loss of protection under the learned intermediary doctrine. In effect, the AMA's House of Delegates has given its implicit support for the decision of the New Jersey Supreme Court in Perez v. Wyeth Laboratories. Companies should not be able to use the learned intermediary doctrine as a defense in the courts to completely escape liability if they are advertising their drugs directly to consumers.

5. The FDA must be adequately funded by the Congress to carry out its oversight function of DTCA and to use its enforcement authority when necessary.
6. For its part, the AMA will continue to educate physicians on their role in identifying and reporting inappropriate DTC advertisements, in cooperating with research studies to better understand and evaluate the impact of DTCA, and to assure they are meeting their ethical duties to their patients in recommending appropriate treatments.

Endnotes

[1]Rosenthal MB, Berndt, ER, Donohue, JM, Epstein, AM, Frank, RG. *Demand Effects of Recent Changes in Prescription Drug Promotion,* Kaiser Family Foundation (June 2003), citing Alperstein and Peyrot 1993; NewsHour/Kaiser/HSPH 2000; Aikin 2002.
[2]Rosenthal et al, citing Borzo 1997; Kaufman and Hoffman 1997; Prevention Magazine, 2001.
[3]Palumbo, FB, Mullins, CD. *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation,* 57 Food & Drug L.J. 423 (2002)
[4]Rosenthal et al, citing Henry J. Kaiser Family Foundation 2000.
[5]United States General Accounting Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations.* GAO-03-177 (October 2002).
[6]Palumbo and Mullins.
[7]Bell RA, Kravitz RL, Wilkes MS. *The educational value of consumer-targeted prescription drug print advertising*. J Fam Pract 2000; 49:1092-1098.
[8]Stephen Leacock, "The garden of folly." New York: Dodd Mead, 1924: 122-31, quoted in N Engl J Med editorial by S. Wolfe, Vol. 346: 524-526, no. 7 (February 14, 2002), *"Direct to Consumer Advertising – Education or Emotion Promotion?"*
[9]*Why Rubin-Ehrenthal sticks exclusively to DTC accounts*. Medical Marketing and Media. September 1999:136-46, quoted in N Eng J Med editorial, 2/14/02.
[10]Bell et al., *Direct-to-consumer prescription drug advertising and the public,* J Gen Intern Med 1999; 14:651-657, quoted in N Eng J Med editorial, 2/14/02.

[11]Davis JJ. *Riskier than we think? The relationship between risk statement completeness and perceptions of direct to consumer advertised prescription drugs*. J Health Commun 2000; 5:349-369, quoted in N Eng J Med editorial, 2/14/02.
[12]*FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, GAO-03-177, General Accounting Office, October 2002
[13]*Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey.* Food and Drug Administration, January 13, 2003. www.fda.gov/bbs/topics/ANSWERS/2003/ANS01189.html.
[14]Rosenthal et al, June 2003, Kaiser Family Foundation report.
[15]GAO report, Oct. 2002.