



# Statement

of the

**American Medical Association**

to the

**Oversight and Investigation Subcommittee  
Energy and Commerce Committee  
U.S. House of Representatives**

**RE: Direct-to-Consumer Advertising: Marketing,  
Education or Deception?**

**Presented by: Nancy H. Nielsen, MD, PhD**

**May 8, 2008**

U.S. House of Representatives  
Committee Energy and Commerce, Subcommittee on Oversight and Investigations

Direct-to-Consumer Advertising: Marketing, Education or Deception?  
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American Medical Association  
Presented by: Nancy H. Nielsen, MD, PhD, AMA President Elect

Direct-to-consumer advertising (DTCA) has become ubiquitous and neither regulatory oversight nor research on its impact have kept pace. As a result, the American Medical Association (AMA) has serious concerns that DTCA is neither balanced nor educational, may adversely affect physician-patient relationships, and contributes to rising health care costs. AMA policy does not oppose “product specific” DTCA if it complies with AMA guidelines. DTC ads must:

- Be indication-specific and enhance consumer education about both the drug and disease.
- Provide a clear, accurate, and responsible educational message.
- Not encourage self-diagnosis or self-treatment.
- Exhibit fair balance between benefit and risk information.
- Present risk information that will be understood by a majority of consumers.
- Not use an actor who portrays a physician, or an actual physician to endorse the drug product, unless there is a prominent disclaimer or disclosure.
- Be targeted for placement so as to avoid audiences that are not age appropriate for the messages presented.

The AMA also supports FDA review and approval of all DTC ads and adequate funding to perform these activities. In addition, the AMA supports a moratorium on DTCA for new drugs until physicians have been appropriately educated about the drug. The length of this moratorium may vary from drug to drug, and should be determined by FDA in negotiations with the manufacturer.

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The American Medical Association (AMA) appreciates the opportunity to provide its views regarding the role of direct-to-consumer advertising (DTCA) in health care. We commend Chairman Stupak , Ranking Member Shimkus, and members of the Subcommittee for convening this hearing. My name is Nancy H. Nielsen, MD, PhD, an internist and President-Elect of the AMA. I am also a clinical professor of medicine and senior associate dean for medical education at the State University of New York at Buffalo School of Medicine and Biomedical Sciences. We look forward to sharing our policy concerning DTCA as well as our perspective on DTCA's impact on the patient-physician relationship, its adequacy as a source of information for patients, and its role in driving health care costs and utilization.

## *Background*

DTCA has become ubiquitous over a very short period of time. According to a recent consumer survey, almost all Americans (91 percent) have seen or heard DTCA.<sup>i</sup> In under ten years, between 1993 and 2002, the percentage of people who reported that they had seen an ad for a prescription drug on television or heard one on the radio more than doubled.<sup>ii</sup> Nearly a third (32 percent) of Americans have talked to a physician about a prescription drug they saw advertised.<sup>iii</sup>

The foregoing is not surprising since the growth in spending on DTCA between 1989 and 2004 has been explosive. In 1989, the pharmaceutical industry spent only \$12 million on DTCA,<sup>iv</sup> and by 2004 spending had dramatically climbed to approximately \$4.45 billion.<sup>v</sup> Pharmaceutical companies have increased spending on DTCA faster than they have increased spending on research and development.<sup>vi</sup> Between 1997 and 2001, spending on DTCA increased 145 percent, while research and development spending increased only 59 percent.<sup>vii</sup> Spending on DTCA grew at an average annual rate of 14.3 percent from 2002 to 2005.<sup>viii</sup>

The sheer frequency and volume of DTCA that now appears on television in particular, including ads for drugs to treat conditions such as erectile dysfunction, has raised questions about the appropriateness of these ads for some consumers, such as children. There is growing concern that many of the television DTC ads lack fair balance; i.e., claims of benefit overwhelm risk information presented in the ads.<sup>ix</sup> This can result in trivialization of the safety risks of prescription drugs. Also, intense advertising for newly

approved drugs with limited safety profiles could potentially lead to significant safety problems.<sup>x</sup> The rofecoxib (Vioxx) case is illustrative of this concern.

The AMA has been, and continues to be, concerned about the possible negative impact of DTCA on the patient-physician relationship, patient safety, and is increasingly concerned about the role that DTCA plays in fueling the increase in health care costs. It is all the more urgent now as Congress grapples with escalating costs and the need to prioritize scarce health care dollars. There is growing alarm that DTCA increases utilization of new and more expensive drugs that all too often have limited safety profiles. The AMA does not believe that the Food and Drug Administration (FDA) has adequate resources to carry out its enforcement role over DTCA since the staffing has not kept pace with the proliferation of DTCA,<sup>xi</sup> nor has Congress provided sufficient funding to support quality, independent research on the impact of DTCA. These concerns are discussed in more detail later in this testimony.

#### *AMA Policy and DTCA*

In June 2006, in light of the rapid proliferation of DTCA, climbing health care costs, and concerns about the negative impact of DTCA on patient-physician relations, the AMA adopted a comprehensive set of recommendations, in addition to guidelines for an appropriate DTC ad, to ensure that DTCA is properly regulated and assessed to ensure it does not adversely impact patient-physician relations, provides appropriate and balanced information, and does not artificially increase health care costs by causing overutilization.

In general, the AMA supports "help-seeking" or "disease awareness" ads (i.e., ads that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA). The AMA opposes "product-specific" DTCA, regardless of medium, that is not consistent with the following guidelines.

- Indication-Specific and Educational. The ad should be indication-specific and enhance consumer education about both the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used.
- Accurate and Objective Information on Risk as well as Benefit. In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the ad should convey a clear, accurate, and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug's or device's approval for marketing. Risk information should be clearly stated and comprehensible to the consumer.
- Prescription Required. The ad should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products.

- Encourage Physician Consultation. The ad should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as "Your physician may recommend other appropriate treatments," is recommended.
- Fair Balance Between Risk and Benefit Information. The ad should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well ease with which people can find, understand, remember, and use the information, should be comparable.
- Clear Communication of Warnings, Precautions, and Potential Adverse Reactions. The ad should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without content and devices designed to minimize or distract from risks, and will help facilitate communication between physician and patient.
- No Actors Playing Doctor Unless Clear Disclaimer Provided. In general, ads should not use an actor to portray a health care professional who promotes the drug or implantable medical device product because this portrayal may be misleading and

deceptive. If actors portray health care professionals in DTCA, a disclaimer should be prominently displayed.

- No Actual Health Care Professionals Unless Clear Disclaimer Provided. The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged, but if utilized, the ad must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.
- Age Appropriate Placement. The ad should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved.
- Comply with FDA Regulations. The ad must comply with all other applicable FDA regulations, policies, and guidelines.

In addition, the AMA's policy includes support for enhanced FDA authority to regulate DTCA. Specifically, the AMA has advocated for FDA authority to review—and pre-approve—all DTC ads for prescription drug or implantable medical device products before pharmaceutical and medical device manufacturers run the ad.

The AMA has called upon the FDA to require that all newly approved prescription drug or implantable medical device products should be subject to a DTCA moratorium until

physicians have been appropriately educated about the drug or implantable medical device. Our policy provides that the time interval for this moratorium on DTCA should be determined by the FDA, in negotiations with the drug or medical device product's manufacturer, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as:

- the innovative nature of the drug or implantable medical device;
- the severity of the disease that the drug or implantable medical device is intended to treat;
- the availability of alternative therapies; and,
- the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.

The AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries 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.

To that end, the AMA also supports actions by Congress to require that the Agency for Healthcare Research and Quality (AHRQ) perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is

detrimental to the public health, then Congress should consider enacting legislation to increase DTCA regulation or, if necessary, prohibit DTCA in some or all media.

(Incidentally, the Institute of Medicine has already recommended that the FDA restrict advertising for newer prescription drugs in a study of drug safety.)<sup>xiii</sup> In such legislation, every effort should be made not to violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.

AMA's current policy recognizes that DTCA is legal and widespread. While the AMA's guidelines for acceptable DTCA have generally been well received by both the FDA and the Pharmaceutical Research and Manufacturers of America (PhRMA), regrettably the member companies of PhRMA have not consistently complied with the AMA's guidelines.

#### *Key AMA Concerns about DTCA*

Significant ongoing concerns and questions about DTCA within the physician community, include: 1) does DTCA provide educational value, are ads fairly balanced, and do they adequately disclose risks to consumers; 2) what is the impact of such ads on patient-physician relationships; and 3) what is the impact of such ads on health care utilization and costs? Each of these concerns/questions is addressed below.

##### *1. Is DTCA Educational and Balanced?*

The bedrock of AMA's 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 ads were informative, they lacked important educational information about the condition and the treatment for which the drug was being promoted.<sup>xiii</sup>

Similarly, researchers in another study reviewed the contents of 67 DTC ads from 10 magazines published between July 1998 and July 1999. They found that the ads rarely quantified a medication's expected benefit, and instead made an emotional appeal.<sup>xiv</sup> In contrast, more than one-half of the ads used data to describe a drug's side effects.<sup>xv</sup> The authors suggested that these DTC ads leave readers with the perception that the drug's benefit is large and that everyone who uses the drug will enjoy the benefit.<sup>xvi</sup>

In yet another study, concerns were raised about the educational value of television DTC ads.<sup>xvii</sup> These investigators reviewed 23 television DTC ads and found the ads provided insufficient information about risks, and that the ads lacked fair balance between benefit and risk information.<sup>xviii</sup> They also found that the ads often used medical terminology that was not consumer-friendly, especially for patients with limited literacy.<sup>xix</sup> More recently, researchers reviewed 31 product-specific DTC TV ads and concluded the ads lacked educational value.<sup>xx</sup> These TV ads provided limited information about the causes

of a disease or who may be at risk, they show characters that have lost control over their social, emotional, or physical lives without the medication, and they minimize the value of health promotion through lifestyle changes.<sup>xxviii</sup>

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 DTCA, 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.”<sup>xxxi</sup> 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.”<sup>xxii</sup>

In addition to assessing the educational value of DTCA, the AMA is concerned that consumers are not consistently receiving 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 risk 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 ads, which require the “brief summary” (which usually is identical text to the risk sections [i.e., warnings, precautions and side

effects] in FDA-approved professional labeling [Package Insert, PI] to be included.

Unfortunately, the “brief summary” has long been criticized by many stakeholders as too difficult for consumers to understand. The AMA has submitted comments to the FDA supporting the presentation of risk information in a more consumer-friendly way, so that key risks about prescription drug products will be better understood.

For television ads, however, studies indicate that DTCA in this medium has not provided fair balance between benefit and risk information. In one study, after viewing DTC TV ads, people were about 80 percent correct in identifying the benefits of the advertised drug, but only 20 percent correct in describing the side effects.<sup>xxiii</sup> In the same study, the researchers found that about three times more sentences were devoted to benefit information when compared to risk information, and that the placement of risk information was such that consumers would be least likely to remember it. Also, an individual would need only about a 6<sup>th</sup> grade reading level to understand the benefits of the advertised drug, but a 9<sup>th</sup> grade level for side effects. The authors concluded that the cognitive accessibility, defined as the ease with which people can find, understand, remember, and use information, was far better for benefit information when compared to risk information in DTC TV ads.

In yet another study, researchers found that the mean television DTC ad length was 46.3 seconds, but only 6.3 seconds on average discussed side effects. Also, the vast majority of the ads (90 percent) placed risk information in the middle or the end of the ad where it would be less likely to be remembered.<sup>xxiv</sup> Some of the ads also were very effective at

using pleasing, not to mention distracting, visuals as the major risk information was being discussed in audio only.

Finally, some studies have shown that patients have potentially dangerous misperceptions about DTCA. One research study suggested that one-half of consumers incorrectly believed that DTC ads are pre-approved by the FDA, and 43 percent incorrectly believed that only completely safe drugs can be advertised directly.<sup>xxv</sup> 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.<sup>xxvi</sup> These perceptions raise the question of whether widespread DTCA is giving consumers a false sense of security that prescription drugs are risk-free.

## *2. What is the Impact of DTCA on the Patient-physician Relationship?*

The AMA remains concerned about the impact of DTCA on the patient-physician 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 Government Accountability Office (GAO), the authors examined a number of consumer surveys and concluded that the percentage of consumers who, in response to a DTCA, 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.<sup>xxvii</sup>

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 ad, come into their offices demanding the physician prescribe the advertised drug for them. 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 FDA survey of physicians, strongly supported by the AMA, 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 DTCA. 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 an ad. 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.<sup>xxviii</sup> Various surveys and limited research studies 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. What is the 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 are paid for, at least in part, by private or public insurance. 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.

Limited studies have concluded that DTCA does, in fact, lead to increased spending on drugs. A 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.<sup>xxix</sup> Each additional dollar spent on DTCA yielding an additional \$4.20 in drug sales in that year.<sup>xxx</sup>

In 2002, the GAO also found that drugs promoted directly to consumers often were among the best-selling drugs, and sales for DTC-advertised drugs 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 was the result of increased utilization rather than price increases.<sup>xxxi</sup> A more recent GAO report in November 2006 also concluded that DTCA appeared to increase prescription drug spending and utilization.<sup>xxxii</sup>

A recent Kaiser Foundation, USA Today, and Harvard School of Public Health consumer survey found that about one-third of consumers have talked to a physician about a prescription drug they saw advertised.<sup>xxxiii</sup> Among this group, 44 percent said their physician prescribed them a drug they asked about, and 54 percent say their physician recommended another prescription drug (resulting in 82 percent who received a prescription either for the drug they asked about and/or another drug).

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 Subcommittee as it examines the consequences of DTCA:

1. The AMA believes there is substantial room for improvement in the educational value of DTCA. In this regard, the AMA urges the pharmaceutical and medical device industries to use and comply with 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 could have a positive impact on health care.
2. The AMA believes that consumers must be better educated to understand the limitations of DTCA. The AMA stands ready to work with the FDA and consumer groups in such an educational endeavor.
3. The AMA supports more independent research on DTCA and, particularly, on its impact on the patient-physician relationship and on health outcomes and costs. In light of recent events involving aggressively marketed new drugs with significant safety risks, the need to examine the impact of DTCA on patient safety also has become a priority. 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 industry and government have an obligation to fund this research. Such research should guide future regulation of DTCA.

4. The FDA should pre-review and approve all DTC ads, and should determine the length of any moratoriums on DTC ads for new drugs and medical devices.
5. For its part, the AMA will continue to educate physicians on their role in identifying and reporting inappropriate DTC ads, 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.

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The AMA is pleased to have the opportunity to share with the Subcommittee the AMA's policy on DTCA and information on the impact it has on the patient-physician relationship, the quality of the information it provides to patients, and the role it may play in escalating health care costs. We look forward to working with the Subcommittee to promote and protect the interests of patients and consumers by ensuring that DTCA is accurate, balanced, and enhances the patient-physician relationship while not causing over utilization or promotion of expensive new drugs with limited safety profiles.

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**Endnotes**

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- <sup>v</sup>Palumbo, FB, Mullins, CD. *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 Food & Drug L.J. 423 (2002)
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- <sup>vii</sup>Government Accountability Office, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*. GAO-07-54 (November 2006).
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- <sup>xvii</sup>*Id.*
- <sup>xviii</sup>Kaphingst KA, DeJong W, 2004.
- <sup>xix</sup>*Id.*
- <sup>xx</sup>Frosch DL, et al. *Creating demand for prescription drugs: A content analysis of television direct-to-consumer advertising*. Ann Fam Med. 5:6-13 (2007).
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- <sup>xxii</sup>*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.
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<sup>xxix</sup>Rosenthal et al, June 2003, Kaiser Family Foundation report.

<sup>xxx</sup>Id.

<sup>xxxi</sup>GAO report, Oct. 2002.

<sup>xxxii</sup>GAO report, Nov. 2006.

<sup>xxxiii</sup>*The Public on Prescription Drugs and Pharmaceutical Companies*, USA Today/Kaiser Family Foundation/Harvard School of Public Health Survey, March 2008.