

# ACP

AMERICAN COLLEGE OF PHYSICIANS  
INTERNAL MEDICINE | *Doctors for Adults*

---

# DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING

---

American College of Physicians  
A Position Paper—2006

# **DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING**

A Position Paper of the  
American College of Physicians

This paper was written by Rachel Groman, MPH, and was developed by the Health and Public Policy Committee of the American College of Physicians: Jeffrey P. Harris, MD, Chair; David L. Bronson, MD, Co-Chair; Cpt. Julie Ake, MC USA; Patricia P. Barry, MD; Molly Cooke, MD; Herbert S. Diamond, MD; Joel S. Levine, MD; Mark E. Mayer, MD; Thomas McGinn, MD; Robert M. McLean, MD; Ashley E. Starkweather, MD; and Frederick E. Turton, MD. It was approved by the Board of Regents on 03 April 2006.

How to cite this paper:

American College of Physicians. Direct-to-Consumer Prescription Drug Advertising. Philadelphia: American College of Physicians; 2006: Position Paper. (Available from American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106.)

Copyright ©2006 American College of Physicians.

All rights reserved. Individuals may photocopy all or parts of Position Papers for educational, not-for-profit uses. These papers may not be reproduced for commercial, for-profit use in any form, by any means (electronic, mechanical, xerographic, or other) or held in any information storage or retrieval system without the written permission of the publisher.

For questions about the content of this Position Paper, please contact ACP, Division of Governmental Affairs and Public Policy, Suite 800, 2011 Pennsylvania Avenue NW, Washington DC 20006; telephone 202-261-4500. To order copies of this Position Paper, contact ACP Customer Service at 800-523-1546, extension 2600, or 215-351-2600.

## Executive Summary

Over the last forty years, the legal environment surrounding prescription drug marketing has changed substantially. More liberal statutes and regulations, combined with a growing emphasis on the patient's role in making health care decisions, expanding profits from drug sales, and avoidance of formulary management have encouraged the pharmaceutical industry to pursue marketing strategies that directly target the consumer. This practice has become known as "direct-to-consumer" (DTC) prescription drug advertising.

As DTC advertising becomes a more common practice, legislators, federal agencies, drug manufacturers, health care professionals, advertising agencies, and consumers continue to debate the virtue of advertising prescription drugs directly to consumers. Some argue that the ads are misleading and encourage the overuse of prescription drugs and the use of more costly treatments. Others argue that DTC advertising provides useful information to consumers, including disease awareness in chronic conditions such as hypertension, diabetes, and depression, which results in better health outcomes. Regardless of one's viewpoint, more research is needed to answer important questions surrounding this form of communication.

Since 1998, ACP has voiced its opposition to the practice of DTC advertising. Recognizing that the practice is currently legal, the College offered broad alternatives to improve the practice. This paper reiterates ACP's opposition to the practice of DTC advertising while offering more specific and practical policy solutions to assist the College in responding to the current regulatory climate. ACP's goal is to ensure that patients have access to truthful, non-misleading information about safe and effective therapeutic products so that they can most effectively be partners in their own health care. However, in its current form, DTC advertising does not serve the best interests of patients or physicians.

**Position 1:** ACP believes that direct-to-consumer advertising of prescription drugs is an inappropriate practice that undermines the patient-physician relationship and often leaves patients confused and misinformed about medications.

**Position 2:** In the absence of legislation or regulation to ban DTC advertising, the FDA should play a stronger role in ensuring that complete, valid, and clear information is provided to the public and in making determinations about whether the commercial information in a DTC ad actually will educate and enhance the health of the public. ACP calls on the federal government to expeditiously strengthen regulations governing DTC ads in the following ways:

- Congress should give the FDA the authority to issue regulations that require review and approval of the content of any DTC advertisement prior to it being released to the public.
- Congress should provide additional resources for the FDA to carry out enhanced oversight and enforcement duties and to study the effectiveness of DTC advertising.
- Congress should give the FDA the authority to regulate “reminder” and “help-seeking” ads.
- The FDA should require at least a two-year moratorium on DTC advertising for newly launched prescription drugs to allow for appropriate monitoring and regulation of drug safety and efficacy.
- Federal regulations should require manufacturers to run corrective ads after receiving both “untitled” and “warning” letters.
- The FDA should take steps toward regulating image selection in ads.
- The FDA should require that information about a drug’s effectiveness, side effects, and contraindications, as well as references to where more comprehensive information can be obtained, be prominently displayed in ads and on labeling and be in a language that is clear and understandable to the general public.
- The FDA should require that ads provide key information to consumers on alternative treatments, such as lifestyle changes.
- DTC ads should be required to contain a statement directing patients to report all adverse reactions to a physician and the FDA at MedWatch, and give the toll-free telephone number and Web address of MedWatch.
- The FDA should require that ads for those drugs approved on the condition of further studies publicly identify that safety concerns have been identified and are being investigated.
- The federal government should sponsor public service ads that do not mention particular treatments, but instead are aimed at increasing the public’s awareness of various under-treated diseases.
- Federal regulations should prohibit the use of DTC ads to promote controlled substances.

**Position 3:** ACP recognizes the value of patient education and supports public and private efforts to make patients—particularly older patients—aware of diseases/conditions, treatment options, indications, and contraindications. The FDA, in cooperation with the medical profession, the pharmaceutical industry, and the pharmacy industry, must further evaluate, define, and measure the impact of DTC ads on patients and physicians and identify ways to ensure that patients and physicians are provided with complete, truthful, and non-confusing health information.

## Background

Direct-to-consumer (DTC) advertising is typically defined as any promotional effort by pharmaceutical companies to present prescription drug information to the general public through the lay media. The ads currently appear in magazines, newspapers, non-medical journals, pharmacy brochures, and direct-mail letters. Increasingly, they also appear on television, radio, videos, and Internet websites. The ads are generally characterized under three categories:

- “Product-claim” ads, which include a product’s name and a therapeutic claim about the product.
- “Help-seeking” ads, which discuss a particular disease or health condition, and advise the consumer to see his/her doctor, but do not mention the product’s name or make any therapeutic claims about a product.
- “Reminder” ads, which mention the product’s name, but make no reference to the health condition the drug is used to treat. These ads are typically directed toward health care professionals, under the assumption that they already know about the advertised product and its use.<sup>1</sup>

DTC ads attempt to educate patients about different health conditions and create a demand for the drug, in part by increasing interaction between patients and their doctors. The ads tend to target individuals with chronic health conditions, such as allergies, high blood pressure, high cholesterol, and depression. Some ads target caregivers and family members of those with the condition, while others target those who may be at risk for a particular disease.<sup>1</sup>

The United States and New Zealand are the only industrialized nations that permit DTC advertising of prescription drugs.<sup>2</sup> In 2004, New Zealand announced a voluntary moratorium on DTC advertising and is seeking to ban the practice effective in 2006.

### ***Spending on DTC Advertising***

Spending on DTC ads more than quadrupled between 1996 and 2003, increasing from \$791 million to \$3.2 billion (these figures include expenditures for DTC ads on television, magazines/newspapers, on radio and outdoors; not spending on physician/hospital detailing, medical journal ads, and the retail value of samples distributed to providers).<sup>3</sup> However, from the first half of 2004 to the first half of 2005, average monthly expenditures for DTC ads decreased two percent.<sup>4</sup> While this decline is most likely a result of the safety concerns associated with NSAIDs and increasing liability risks, it represents the first time that pharmaceutical companies have reduced expenditures for DTC ads in six years.

In 2003, spending on DTC advertising made up approximately 13 percent of all promotional spending for pharmaceuticals. If the retail value of samples distributed to physicians is subtracted from the total amount of promotional spending, DTC advertising made up 36 percent of all promotional spending in 2003, second only to the cost of physician detailing.<sup>3</sup>

The pharmaceutical industry reports that spending on research and development exceeded promotional spending every year for the last five years.<sup>1</sup> However, a 2002 Government Accountability Office (GAO) report found that between 1997 and 2001, pharmaceutical industry spending on DTC advertising increased at a much greater rate than outlays for research and development.<sup>5</sup>

Decisions on how pharmaceutical companies set prices and whether they pass the costs of DTC advertising on to consumers are proprietary,<sup>1</sup> making it difficult to show a link between advertising expenditures and drug prices.

### ***Impact of DTC Advertising***

In 2004, surveys by the Food and Drug Administration (FDA) of both patients and physicians lead the agency to conclude that DTC advertising affects information seeking, health care visits, questions and/or requests of physicians, and ultimately the public health. The surveys found that most patients (81 percent) were aware of ads and that the ads contained both benefit and risk information. The ads prompted 43 percent of respondents to look for more information about a drug or medical condition (of which 89 percent sought information from their physicians), but there was limited evidence of increased visits to physicians as a result of DTC ads.<sup>6</sup> Only 4 percent of more than 1,800 patients surveyed said they visited their doctor because of a DTC ad (health-related concerns, such as previous conditions and scheduled check-ups, were the most common reasons given for a doctor visit, which is not to say that the ad did not encourage them to make those appointments). The FDA surveys also found that over the past five years physicians, particularly primary care physicians, noted an increase in questions about prescription drug treatments, with 85 percent saying patients asked often or all the time, and 62 percent reporting that patients asked frequently about generic drugs.<sup>6</sup>

An annual study by *Prevention Magazine* reported in 2004 that 62.4 million patients talked to their doctors about advertised medicines, and of these, 16.2 million asked for an advertised medicine. Older Americans were found to be somewhat less likely to talk with their doctors about advertised medicines than “baby boomers” (27 percent vs. 36 percent).<sup>7</sup>

Other studies have estimated that between 4 and 6 percent of the U.S. adult population – 8.5 million to 12.6 million people in 2001 – appear to have received a prescription for a drug as a *direct result* of a DTC ad.<sup>8</sup>

Even if patient visits to physicians promoted by DTC ads do not result in a prescription for the advertised drug, the ads may still encourage patient-physician interactions and encourage patients to ask better questions of their physician. A 2003 Harvard study found that DTC advertising helped one in four patients who asked about an advertised product during a doctor visit get a diagnosis for a previously unknown medical condition. Approximately 43 percent of these new diagnoses were for high priority conditions such as asthma, high blood pressure or diabetes.<sup>9</sup> *Prevention Magazine's* 2005 study found that of the 65 million people who talked with their physician after seeing a DTC ad, 29 million mentioned a condition for the first time.<sup>10</sup> According to the FDA surveys, DTC ads can improve patient compliance with physician advice, particularly if physicians remind patients to take the medication as prescribed. The ads also encouraged patients to seek information about a given disease from sources other than their physicians.<sup>6</sup>

There is no dispute that DTC advertisements reach their audience, motivate consumers, and result in requests for medication. What is questionable is whether those requests result in better and more appropriate care.

## **FDA Regulation**

The FDA currently has the authority to regulate “product-claim” ads, but only once they have been marketed to the public. According to regulations, therapeutic claims cannot be false or misleading. Print ads must contain all the risk information described in the drug’s FDA-approved label, including major side-effects, contraindications, and precautions. Broadcast ads must directly state major risk information and must direct consumers to other sources from which they can access more complete risk information.

Although the FDA does not have the authority to regulate “help-seeking” or “reminder” ads, the agency continues to monitor these ads and issue draft guidances to ensure there is no implication of a product claim.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938, the FDA was given broad authority to consider drugs misbranded if their labeling or advertising is false or misleading in any way. In 1962, Congress added a section to the Act, which gave the FDA specific authority to regulate prescription drug promotional labeling and advertising, including DTC ads. The 1962 law specifically prohibits the FDA from issuing any regulations that would require prior approval of the content of any advertisement or promotional material. As a result, drug manufacturers are only required to submit advertisements to the FDA once they are made available to the public. The FDA’s post-market authority over advertising and promotional materials is unique. With product labeling, for instance, the FDA is required to review and approve the wording *before* the product can be marketed to the public. Product labeling includes professional labeling, which is usually more technical and directed at health care professionals, and patient labeling, such as the Patient Package Inset (PPI), which is used to instruct patients about the safe use of the product in an easily understood language based on the professional labeling.<sup>1</sup>

Responding to its expanded authority, the FDA issued regulations stating that advertisements must have the following basic attributes:

- They cannot be false or misleading;
- They must present a “fair balance” of information about the risks and benefits of using the drugs;
- They must contain facts that are material to the product’s advertised uses (i.e., they must not recommend or suggest any use of a drug that is not listed in the approved drug’s labeling and therefore has not been approved by the FDA); and
- They must contain a “brief summary” of the drug that includes all risk-related information in the drug’s labeling, such as side effects, contraindications, and precautions.<sup>1</sup>

When the FDA first began regulating drug marketing, advertising took place mostly in the form of printed materials directed at physicians. Physicians were expected to act as “learned intermediaries,” interpreting drug information for the general public (see section on **State Regulation of DTC Advertising** for a discussion of the Learned Intermediary Rule). But, cultural shifts emphasizing the patient’s role in making medical decisions and expanding profits from drug sales encouraged the industry to pursue more direct marketing strategies.<sup>11</sup> By the 1980s, drug ads began to appear on television and radio and began to shift attention from health care professionals to consumers.

In 1997, the FDA issued guidance on how existing regulatory requirements apply to broadcast advertisements. Since it was nearly impossible for drug



manufacturers to include the kind of detailed information required of print ads in commercial broadcasts, which are of limited length (30 to 60 seconds), the FDA made an exception. Broadcast ads are not required to include all product labeling information, but instead must include a “major statement,” which mentions the advertised product’s most important risks. The major statement is required to be in the audio portion of the advertisement, but could also be in the video portion. Broadcast advertisements must also either list all of the drug’s risks (like print ads) or ensure that consumers are at least told where they can access an advertised product’s complete labeling. If the latter option is chosen, the FDA recommends that pharmaceutical companies adequately provide the general public with four sources of this information: referral to an Internet site, toll-free number, health care provider, and other concurrent print sources with large circulation. According to the FDA, this multifaceted approach will best ensure adequate dissemination of product labeling.<sup>12</sup>

Following the FDA’s 1997 guidance, drug manufacturers turned increasingly to television to reach consumers. According to the GAO, the television ad share of DTC pharmaceutical advertising increased from 25 percent to 64 percent between 1997 and 2001.<sup>5</sup>

In 2004, the FDA issued three draft guidances to further improve the information presented in DTC print ads. The first guidance clarified the “brief summary” requirement in print ads. To fulfill the “brief summary” requirement, manufacturers were often including in the ad the entire section of the approved professional labeling. Concerned that the technical language and volume of material presented discouraged consumers from reading the information, the FDA proposed that manufacturers choose among three ways to present the information required in the “brief summary:” 1) print the FDA-approved *patient* labeling in full; 2) print a portion of the patient labeling, including risk information but omitting certain items, such as directions for use; 3) modify the “highlights” section of professional labeling so that it is consumer-friendly.<sup>13</sup> All three of these options still require the manufacturer to print all risk-related information, including the three to five most common non-serious adverse reactions most likely to affect the patient.

The second guidance clarified when the FDA has jurisdiction over “help-seeking” and “reminder” ads. It explains that “help-seeking” and “reminder” ads must appear distinctly separate and not sequenced in order to avoid coming under the regulations for a “product-claim” ad. The guidance also addresses the separation needed between the two types of ads—in space for print ads, and in time for TV ads.<sup>14</sup> Both the FDA and the Federal Trade Commission (FTC) continue to watch for those who have a commercial interest in funding a disease awareness ad, such as manufacturers of the only product in a therapeutic category.<sup>1</sup>

The third guidance discussed the regulation of medical device marketing, which is beyond the scope of this paper.

In recent years, the pharmaceutical industry has begun to promote a number of controlled substances – including a schedule II stimulant and several schedule IV products – through DTC advertisements. In terms of DTC advertising, federal law and FDA regulations do not distinguish between controlled substances and other prescription drugs. However, as of 2002, four states (Illinois, Kentucky, Missouri and Rhode Island), and possibly five (Florida) had laws prohibiting DTC advertising of any controlled substances (see section below on **State Regulation of DTC Advertising**).<sup>15</sup> Although the Drug Enforcement Administration (DEA) does not have the statutory authority to ban DTC advertising, it has made public statements opposing DTC advertisements of

controlled substances. In testimony before a House Subcommittee in 2001, former DEA Administrator Asa Hutchinson blamed the “disproportionate abuse of OxyContin,” a controlled release narcotic pain reliever, on the aggressive marketing and promotion by the manufacturer and stated that the company “accentuated the problem by suggesting that physicians prescribe the drug as a substitute for a variety of less addictive existing medications.”<sup>16</sup>

### **FDA Enforcement**

FDA regulations are enforced principally through the FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC). In 2003, DDMAC received about 38,000 of these submissions from drug sponsors (32,000 were promotional materials directed at health care professionals, such as trinkets, ads in medical journals, and labeling, and 6,000 were promotional material directed at consumers, such as booklets and videos). Although not required, pharmaceutical companies often voluntarily submit draft promotional materials to DDMAC for review prior to releasing them to the public because of the high cost of possibly having to make changes after an ad is released. In 2003, DDMAC reviewed 161 broadcast and 221 print DTC ads that had been voluntarily submitted by manufacturers prior to public release.<sup>1</sup>

Once an ad is made public, the FDA has the authority to review the accuracy of claims in a drug’s promotion and take enforcement action. If an ad violates a federal statute or regulation, the FDA typically sends a letter to the manufacturer requesting that the ad be withdrawn. An “untitled letter” sent by the FDA directs the manufacturer to stop the ad immediately. For more serious violations, the FDA sends a “warning letter,” directing the manufacturer to not only stop the ad but to also take corrective action by disseminating information to the audience of the original promotional material. In 2004, the FDA sent 23 letters concerning promotional materials that did not comply with regulations, twelve of which were the more serious “warning letters.”<sup>11</sup>

For cases that cannot be rectified by a “warning letter,” the FDA may work with the Department of Justice (DOJ) to seek an injunction against the company, criminally prosecute the company, seize the misbranded product, or withdraw the drug’s approval. Rarely is a case brought to court for resolution. The FDA, itself, has no ability to impose civil monetary penalties or fine drug manufacturers that break the rules with DTC ads.<sup>17</sup>

Court rulings examining the FDA’s authority to regulate DTC ads have emphasized that the agency should not impose unnecessary restrictions on manufacturers’ commercial speech. The courts rationalize these protections on the grounds that commercial speech provides information to the public.

In September 2004, Merck and Company voluntarily withdrew its drug Vioxx (rofecoxib: a COX-2 inhibitor, the newest class of NSAIDs) from the market because studies had shown elevated heart attack and stroke risk with prolonged use. Three months later, the FDA requested that Pfizer, Inc. voluntarily suspend DTC advertising on Celebrex, another COX-2 inhibitor, while the agency evaluates new and conflicting data on adverse events associated with the drug. Pfizer was also asked to include a boxed warning in the Celebrex package insert stating an increased risk of cardiovascular events and potentially life-threatening gastrointestinal bleeding associated with its use. The FDA directed manufacturers of all other prescription NSAIDs to revise their labels to include the boxed warning, as well as a medication guide for patients to increase awareness of the potential for adverse events associated with this class of drugs. Manufacturers of all over-the-counter NSAIDs were asked to revise

labels to include more specific risk information and safe uses of the drug. The FDA also encouraged physicians to consider alternative therapies as they evaluate their individual patients' needs and requested that manufacturers modify information provided to physicians to reflect this recommendation.

In 2005, the FDA announced the creation of a new independent Drug Safety Oversight Board (DSB) to oversee the management of drug safety issues and provide emerging information to providers and patients about the risks and benefits of medicines. A new "Drug Watch" Web page was also created to increase the use of consumer-friendly emerging data and risk information by both health care professionals and patients.

Around the same time, Senate Majority Leader Bill Frist (R-TN) proposed a voluntary two-year moratorium on DTC drug advertising in an effort to cap spiraling drug costs and promote patient safety. PhRMA, the pharmaceutical industry's trade association, responded by issuing voluntary principles to guide the industry's use of DTC ads. The voluntary principles, which took effect in January 2006, call on member companies to submit DTC television ads to the FDA before releasing ads for broadcast and to precede DTC ads with greater efforts to educate health professionals about the new drugs, among other things. Although not mandatory, the principles have been endorsed by more than twenty individual drug companies. While PhRMA claims that several of the new principles exceed FDA regulations, others, including Senator Charles Grassley (R-IA) and the consumer advocacy group Consumers Union, say the principles fall short of dealing with the issue in any significant way.<sup>18</sup>

To account for an upsurge in the number of ads submitted to the FDA since PhRMA's advertising principles went into effect, the agency recently announced it was making a major change to how it reviews DTC ads. Rather than review ads based on when they arrive at the FDA, the agency will now focus first on newer claims. Specifically, the agency will focus first on: ads for drugs that are new or have never been advertised on television; drugs used for new patient populations or new purposes; and instances where new risk information is available and where there are new effectiveness claims. The agency reports difficulty handling the growing number of ads given their limited resources and staff turnover.<sup>19</sup>

Various manufacturers have also taken voluntary action in response to the principles. Pfizer announced that it will not advertise new drugs to consumers until they have been on the market for six months, and, along with Eli Lilly and Company, promised to limit ads for erectile dysfunction medications to appropriate audiences. AstraZeneca publicly stated that all DTC ads should be submitted to the FDA for review before they run.

### **State Regulation of DTC Advertising**

The majority of states can be understood as implicitly prohibiting DTC advertising of a wide array of drugs through adoption of the Uniform Controlled Substances Act, which bans false advertising of drugs. Several states prohibit DTC advertisements for specific types of drugs, such as those related to abortion, sexual diseases or sexual disorders, while others prohibit DTC advertising of specifically named drugs. However, a 1999 decision of the U.S. District Court for the Northern District of Illinois (*Knoll Pharmaceutical Company v. Sherman*) suggests that state regulation of DTC drug advertising may be unenforceable. In that case, the court held that a state statute barring the advertising of certain drugs was unconstitutional.<sup>15</sup>

The growing use of DTC advertisements over the last two decades has also changed the dynamic of state product liability laws. Under a common-law doctrine called the learned intermediary rule (LIR), drug manufacturers are protected from liability for adverse consequences to the patient if they adequately warn the prescribing physician of known health risks resulting from the administration or ingestion of prescription medications. Therefore, drug manufacturers have had, up until recently, no legal duty to warn consumers directly of drug risks. But now that patients are increasingly involved in health care decision-making, the learned intermediary rule is under scrutiny. In 1999, New Jersey became the first and only jurisdiction to adopt a DTC advertising exception to the learned intermediary rule. In *Perez v. Wyeth Laboratories*, a case in which the plaintiffs filed suit against a pharmaceutical manufacturer for injuries sustained as a result of using the implanted Norplant contraceptive device, the New Jersey Supreme Court held that “a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.” The court maintained that DTC advertising has so fundamentally transformed physician and patient roles in prescribing decisions that the traditional justifications for the LIR no longer apply. Although not binding on other states, the *Perez* decision is likely to prove influential since the New Jersey Supreme Court is considered a bellwether court in crafting product liability law.<sup>20</sup>

### ***ACP’s Position on Physician-Industry Relations***

ACP’s Ethics and Human Rights Committee produced a two-part position statement to help guide individual physicians, medical education providers, and medical professional societies in making ethical decisions about interacting with industry. In Part 1, the College offers recommendations to individual physicians, mainly clinicians and clinician-researchers, regarding acceptance of gifts and other financial relationships with industry. Part 2 addresses medical education providers and medical professional societies that accept corporate funding for organizational projects or membership events, such as meetings and symposiums. ACP believes that the primary purpose of entering into relationships with industry should be the enhancement of patient care and medical knowledge. While the ethics of medicine and the ethics of business sometimes diverge, both are legitimate, and a thoughtful collaboration of physicians and industry can result in the best of patient care.<sup>21 22</sup> These position statements are available at:

- **Physician–Industry Relations. Part 1: Individual Physicians**  
[www.annals.org/cgi/content/full/136/5/396](http://www.annals.org/cgi/content/full/136/5/396)
- **Physician–Industry Relations. Part 2: Organizational Issues**  
[www.annals.org/cgi/content/full/136/5/403](http://www.annals.org/cgi/content/full/136/5/403)

## Positions

Since 1998, ACP has voiced its opposition to the practice of DTC advertising. Recognizing that the practice is currently legal, the College offered broad alternatives to improve the practice. In September 2005, ACP's Health and Public Policy Committee decided that the College's position statement on DTC advertising should be strengthened by offering more specific and practical policy solutions to assist the College in responding to the current regulatory environment.

**Position 1:** ACP believes that direct-to-consumer advertising of prescription drugs is an inappropriate practice that undermines the patient-physician relationship and often leaves patients confused and misinformed about medications.

ACP believes that DTC advertising creates an artificial demand for drugs and undermines the patient-physician relationship as patients place undue pressure on physicians to prescribe an advertised product. Advertisements motivate patients to request prescriptions in up to seven percent of primary care encounters — a rate that adds up to millions of requests a year. According to a FDA study, between 74 percent and 77 percent of doctors prescribed the requested drug when a specific drug was requested.<sup>7</sup> A more recent report in the *Journal of the American Medical Association* concluded that physicians are significantly more likely to write prescriptions for patients who ask for brand-specific antidepressants (requests frequently inspired by DTC ads) than for patients making general requests for medication or no requests at all.<sup>23</sup>

The FDA found that when ads are discussed, the majority of physicians report no pressure to prescribe a specific drug and that most physicians report being comfortable with denying medications, particularly when the requested drug was not right for the patient.<sup>6</sup> However, the FDA also found that although few physicians reported excessive pressure to prescribe requested drugs, nearly half reported feeling at least a little pressure and 28 percent of those surveyed admitted the ads can lead to doctor-patient tension.<sup>6</sup> Still, physicians are not so much threatened in terms of their medical judgment, as they are burdened by the time it takes to clarify such requests.

ACP members report that patients continually attempt to influence their own treatment regimens based on what they see in the media, rather than by what may be the best medical treatment option for them. Physicians end up spending valuable time fielding requests, clarifying misconceptions, and explaining other, sometimes more effective treatments. Time spent with the patient gets diverted from patient education to negotiation and when a coveted drug is not part of a patient's health plan formulary, patients may pressure physicians to make a case for medical necessity—another round of hassle and effort for the physicians. Withholding something a patient wants often builds mistrust of the physician. Such interactions result in a subtle but chronic adversarial element in the doctor-patient relationship that takes a substantial emotional toll on physicians.

According to the FDA, 65 percent of physicians believe patients misunderstand the relative risks and benefits of a drug advertised through a DTC ad and 75 percent say the ads lead patients to overestimate the medical value of the drugs. The FDA also found that 38 percent of physicians surveyed felt that DTC ads caused patients to question their diagnoses.<sup>6</sup> The rapid-fire listing of adverse events in DTC ads may cause so much confusion that patients quit taking needed medications without consulting their physician.



DTC ads also encourage inappropriate and unnecessary consumption of certain drugs, resulting in higher drug costs overall. For example, the ads often promote expensive brand-name products when less-expensive but therapeutically equivalent generic products are available. A national survey found that when a specific drug requested by a patient was prescribed, 46 percent of physicians said that it was the most effective drug, while 48 percent said that others were equally effective.<sup>24</sup> Such unnecessary spending further weighs down an already costly health system.

Spending on prescription drugs is the fastest growing component of the health care budget. While proponents of DTC advertising feel the practice fosters competition among products, resulting in lower drug costs and increased access to consumers, the GAO has concluded that DTC advertising appears to increase prescription drug spending and utilization. This increased spending is primarily due to increased utilization, rather than increased prices.<sup>6</sup> A 2000 analysis of prescription volume and sales of advertised drugs compared to non-advertised drugs found that doctors wrote 25 percent more prescriptions for the 50 most heavily DTC-advertised drugs compared to 4.3 percent more scripts for all other drugs combined. Sales of the top 50 most heavily advertised drugs rose an aggregate 32 percent from 1999 to 2000 compared to 13.6 percent for all other drugs combined. Increases in the sales of these 50 most heavily advertised drugs accounted for almost half (47.8 percent) of the overall \$20.8 billion rise in spending on drugs in the retail sector from 1999 to 2000.<sup>8</sup> The GAO also found that between 1997 and 2001, the best-selling drugs were those most heavily advertised. It estimated that a ten percent increase in DTC advertising translates into a one percent increase in sales for that class of drugs, a substantial amount for drug classes with sales in the billions of dollars.<sup>5</sup> Although such research proves no direct cause and effect link between DTC ads and increasing drug use and spending, it is highly suggestive.

A lawsuit recently filed against Pfizer claimed it unlawfully induced consumers, through a multi-million dollar promotional campaign, to use its brand-name drug Lipitor by marketing the cholesterol-lowering drug as a means to prevent heart disease in women and the elderly, despite the absence of clinical evidence. The lawsuit alleges the marketing drive created an artificial demand for the drug and resulted in billions of dollars of unnecessary costs for consumers, who received no benefit from the drug, and for their health insurers. The complaint seeks an injunction to stop Pfizer from marketing Lipitor to individuals who receive no benefit from the drug and requests monetary reimbursement for consumers and third-party payers who were allegedly misled into purchasing Lipitor as a result of the deceptive marketing campaign.<sup>25</sup>

There seems to be a recent deterioration in the public's perception of DTC advertising. The FDA surveys found that in 2002 versus 1999, fewer people (18 percent versus 27 percent) asked their physicians about previously untreated conditions, fewer people found DTC ads useful in conversations with their physicians and with health care decision making, and fewer people held positive views of DTC ads.<sup>6</sup> Those with negative reactions to the ads felt the ads overstate drug efficacy and do not present a balance of benefit and risk information.

**Position 2:** In the absence of legislation or regulation to ban DTC advertising, the FDA should play a stronger role in ensuring that complete, valid, and clear information is provided to the public and in making determinations about whether the commercial information in a DTC ad actually will educate and enhance the health of the public. ACP calls on the federal government to expeditiously strengthen regulations governing DTC ads in the following ways:

- Congress should give the FDA the authority to issue regulations that require review and approval of the content of any DTC advertisement prior to it being released to the public.
- Congress should provide additional resources for the FDA to carry out enhanced oversight and enforcement duties and to study the effectiveness of DTC advertising.
- Congress should give the FDA the authority to regulate “reminder” and “help-seeking” ads.
- The FDA should require at least a two-year moratorium on DTC advertising for newly launched prescription drugs to allow for appropriate monitoring and regulation of drug safety and efficacy.
- Federal regulations should require manufacturers to run corrective ads after receiving both “untitled” and “warning” letters.
- The FDA should take steps toward regulating image selection in ads.
- The FDA should require that information about a drug’s effectiveness, side effects, and contraindications, as well as references to where more comprehensive information can be obtained, be prominently displayed in ads and on labeling and be in a language that is clear and understandable to the general public.
- The FDA should require that ads provide key information to consumers on alternative treatments, such as lifestyle changes.
- DTC ads should be required to contain a statement directing patients to report all adverse reactions to a physician and the FDA at MedWatch, and give the toll-free telephone number and Web address of MedWatch.
- The FDA should require that ads for those drugs approved on the condition of further studies publicly identify that safety concerns have been identified and are being investigated.
- The federal government should sponsor public service ads that do not mention particular treatments, but instead are aimed at increasing the public’s awareness of various under-treated diseases.
- Federal regulations should prohibit the use of DTC ads to promote controlled substances.

The promise of DTC prescription drug advertisements lies in their potential to educate consumers about medical conditions and the possibility of treatment. But this promise can only be fulfilled if consumers are given clear and accurate information. The responsibility for ensuring that this occurs falls on the FDA, but recent congressional investigations have indicated that the agency is failing at this task, as FDA enforcement actions against false and misleading ads have declined precipitously in recent years.<sup>26</sup>

One of the main reasons the agency has difficulty meeting its responsibilities is because the current regulatory structure and funding surrounding DTC advertising are weak. For one, the current retrospective process gives too much leniency to the pharmaceutical companies and allows them to get their message out to the public before the FDA has a chance to deem the appropriateness and

accuracy of the information contained in the advertisements. Additionally, according to the GAO there is no mechanism in place to verify that the FDA receives all newly disseminated ads from drug companies.<sup>5</sup>

Compounding the problem is that the FDA lacks the resources to provide adequate oversight of DTC ads. In 2002, Congress authorized more than a doubling of the budget available to the DDMAC in fiscal year 2005 (to \$5.5 million) to be used to monitor broadcast and Internet ads more vigilantly and to ensure that the messages conveyed do not mislead consumers.<sup>27</sup> However, these increased funds have not been requested by the current administration, and the DDMAC continues to be under-funded. Insufficient resources affect the FDA's ability to review drug ads for misleading content in a timely manner. A division of 40 employees at the FDA is tasked with reviewing 40,000 complex medically sensitive advertisements, which leads to many ads running without formal review.<sup>28</sup> The agency is also unable to quickly issue letters following the identification of a violation. Prior to a recent policy change that required that all letters be reviewed by the FDA's Office of the Chief Counsel, the agency issued letters within a few days after a violation was identified. Following the change, reviews took between 13-78 days. Reviews have now been streamlined to five days for "warning letters" and 15 days for "untitled letters."<sup>29</sup> As DTC ads increase in frequency, FDA violation letters sent to manufacturers are dropping—from 157 in 1998 to 24 in 2004—suggesting that the agency is not equipped for the job.<sup>17</sup>

ACP believes that Congress should give the FDA the authority to require pre-marketing approval of DTC advertisements and the authority to regulate both "help-seeking" and "reminder" ads. FDA regulation of DTC ads should be based on evidence-based medicine practices, with input from practicing health professionals. Both pre-market and post-market FDA regulation of DTC ads should be timely and the entire regulation process must be transparent.

It is also critical that the FDA more carefully monitor the intent of DTC advertisements to ensure that they have a clear educational purpose (i.e., inform patients about a particular condition or the availability of a new treatment) rather than a purely promotional purpose (i.e., aimed at "brand recognition"). ACP believes that DTC advertisements are most effective as a patient education tool when their primary intent is to raise disease and treatment awareness and encourage patients to seek more information from their physician. Ads with solely promotional intentions—even when they are not technically untruthful or misleading—may, by omission, emphasis, or emotional appeal, spur consumer purchasing patterns that are contrary to public health goals. The FDA should also take steps toward regulating image selection in ads, since imagery can be as powerful as any wording. The FDA should pay particular attention to broadcast ads to ensure their non-verbal and visual presentations do not make or imply inappropriate claims. Furthermore, ACP recommends that the federal government sponsor public service ads and develop a system where drug manufacturers may support an objective public service announcement fund to educate the public about under-treated and under-diagnosed diseases and conditions.

The lack of fair balance in DTC ads is a major concern of the College that may result from the currently weak regulatory structure. The ads often provide insufficient and unclear information about the appropriateness of the drug, the risks and benefits, or comparable and more cost-effective options. A Duke University study even warned about the danger of ads that employ distracting graphics, since they often obscure important risk information. The end result is that patients are often confused and misinformed about medications and



falsely assured that drugs are safer than they are. In the same Duke University study, 80 percent of those queried could remember what the drug was supposed to treat, but only 20 percent could describe the side effects.<sup>29</sup>

To ensure effective consumer education, the FDA should require that ads include essential information, such as information regarding a drug's indications, contraindications, effectiveness, and side effects, and key information on alternative treatments, such as lifestyle changes. Ads should also include comparative quality data, thus creating a basis for more informed consumer choice. Furthermore, the FDA should require that information directing patients to additional resources be prominently displayed in an ad. This will ensure that patients with different information-seeking needs and capabilities have adequate access to other sources of information and are able to make evidence-based assessments of drug effectiveness.

DTC ads currently provide limited information on how well the drug works. While the FDA requires that information regarding a drug's potential harms be presented, information on the drug's benefit is not required (the ad must simply note the drug's indications). As a result, most ads assert that drugs work using vague, qualitative terms (for example, "Zyrtec works" and "lower your number") rather than presenting actual data. Only about a tenth of DTC ads provide data about drug benefits in either the ad or the accompanying brief summary.<sup>30</sup> Concerned that the absence of benefit data may lead some patients to assume that the drug always works, a 2004 study set out to evaluate the effectiveness of including a "prescription drug benefit box" in a DTC ad. The box was simply a table presenting the proportion of people experiencing various outcomes with and without the drug, based on the main randomized trials of the drug. The study found that most participants rated the information as "very important" or "important" and almost all found the data easy to understand. Perceptions of drug effectiveness were much lower for ads that incorporated the benefit box than for ads that did not.<sup>30</sup>

There is a growing consensus among health professionals and consumer advocates that heavily promoting new drugs that have not been widely tested among patients, and thus carry little definitive data on safety and outcomes, could have a deleterious effect on the public's safety. The recent NSAIDs incident heightened this concern. When Merck voluntarily withdrew its drug Vioxx (rofecoxib) from the market, the company had already spent more than \$100 million per year on DTC advertising of the drug, annual sales had topped \$2.5 billion, and more than 80 million patients had already taken the drug. Even though rofecoxib was approved in 1999 on the basis of data submitted to the FDA, the data were not submitted to a peer-reviewed journal until the following year and did not appear in print until November 2000, one and a half years after commercial approval had been granted (and even at that point the cardiovascular data reported in that article were incomplete). It was not until February 8, 2001, two years after the FDA approved rofecoxib, that the FDA Arthritis Advisory Committee met to discuss concerns about the potential cardiovascular risks associated with the drug. Over the five-and-a-half-years that the drug was on the market, various epidemiologic studies confirmed the concern about the risk of myocardial infarction and serious cardiovascular events associated with the drug. Nevertheless, the only significant action taken by the FDA occurred in April 2002, when the agency instructed Merck to include certain precautions about cardiovascular risks in its package insert. More recent studies conducted since the drug was taken off the market suggest that there may be tens of thousands of patients who have had major adverse events attributable to rofecoxib.<sup>31</sup>

In response to the FDA discovering safety issues with several highly-marketed drugs, ACP recommends that the FDA require that pharmaceutical companies refrain from running DTC ads for at least two years after a new drug enters the market. This delay would allow for the FDA to consider various sources—such as post-approval studies, risk-benefit analyses, adverse event reports, and any clinical or observational studies—to make evidence-based assessments of drug safety and efficacy. This delay would also give physicians additional time to understand more fully the appropriate use of medications. Following the two-year moratorium, the FDA, with the input of the medical community, should be responsible for determining if the drug has significant adverse health effects and whether DTC advertising of the product should proceed.

ACP believes that if a moratorium on DTC drug advertising were implemented, drug manufacturers would shift their focus back to more appropriate educational efforts aimed at physicians. Although a moratorium on advertisements could be costly for the pharmaceutical industry, drug companies would save on the marketing costs and potential damages from litigation should a drug prove to be unsafe.

The FDA should also require that ads for drugs approved on the condition of further studies publicly identify that safety concerns have been identified and are being investigated. Drugs that receive expedited approval from the FDA are done so on the condition that post-market studies be carried out. These so-called Phase 4 studies are used to gather additional information about a drug's safety, efficacy, or use and the outcome of these studies can lead to changes in how a drug is made, prescribed, and used. However, the FDA recently found that drug companies have launched barely a third of the follow-up studies they agreed to undertake once their new medications were on the market.<sup>32</sup> Given this finding, it is critically important that advertisements for such drugs warn consumers that studies are still pending and that safety concerns exist.

To further ensure the public's safety, ACP recommends that manufacturers who receive both "warning" letters and the less serious "untitled" letters be required to run corrective ads. The manufacturer should be required to run corrective ads in the same media outlets in which the ad originally ran and for a duration that reflects the gravity of the infraction.

The FDA must also limit DTC advertising of controlled substances, which are by definition susceptible to abuse and dangerous when used incorrectly. The very purpose of advertising is to increase demand and sales of drugs. Demand for controlled substances should not be driven by commercial considerations, but instead it should be the result of medical consultation and informed medical opinion as to a patient's need.

In marketing their sleeping pill Lunesta (a controlled substance), drug manufacturer Sepracor, Inc. equates occasional insomnia with a "disease" requiring treatment with their product, which it claims can be "used long term without addiction." Insomnia is a common disorder. However, chronic insomnia, in which symptoms last for at least one month, has a prevalence of only ten to fifteen percent.<sup>33</sup> Still, a record 43 million sleeping-pill prescriptions were filled in the U.S. in 2005, fueled by almost \$300 million in drug companies' ad spending and resulting in more than \$2 billion in sales.<sup>34</sup> The only long term (6 month) study to evaluate the safety and efficacy of Lunesta had no objective measures to determine if the patients developed tolerance to the drug, but merely relied on self-reporting.<sup>35</sup>

In light of the special considerations afforded controlled substances in federal law, ACP believes that DTC advertising of controlled substances should not be permitted and urges the drug industry to voluntarily cease this practice until a regulatory or Congressional ban is in place.

Finally, Congress should provide the FDA with additional resources to strengthen its regulation of DTC ads and to study the value of DTC ads to both patients and their health care providers. There are particular areas of research that require special attention, such as Web-based DTC advertisements, which represent a newer yet key component of DTC advertising. Since the FDA requires pharmaceutical companies to make complete information available to the public and Web sites are the most common medium for doing so,<sup>36</sup> the FDA should evaluate whether current regulations are appropriate for Web-based DTC advertisements.

The passage of a Medicare drug benefit in November 2003, which dramatically expands the market for pharmaceuticals, adds some urgency to the need for more informative DTC drug ads. Given the government's fiduciary responsibility to taxpayers to ensure that their tax dollars are not wasted and to assure the safety and quality of pharmaceuticals, the government could require, as part of any purchasing agreement, that drug manufacturers disclose information about safety and comparable effectiveness as part of their DTC advertising.<sup>27</sup>

**Position 3:** ACP recognizes the value of patient education and supports public and private efforts to make patients—particularly older patients—aware of diseases/conditions, treatment options, indications, and contraindications. The FDA, in cooperation with the medical profession, the pharmaceutical industry, and the pharmacy industry, must further evaluate, define, and measure the impact of DTC ads on patients and physicians and identify ways to ensure that patients and physicians are provided with complete, truthful, and non-confusing health information.

Effective patient education of health conditions and treatment options encourages consumers to seek treatment and to discuss their health problems with their health care provider. Good information also allows patients to be better informed in their interactions with physicians, empowering patients and giving them a greater role in health care decision-making. Patients ask meaningful health care questions and have better context for answers. Enhanced communication and overall patient-physician encounters increase the likelihood of new diagnoses for often under-diagnosed and under-treated conditions<sup>37</sup>—such as hypertension, diabetes, and depression—and minimize the chance of inappropriate prescribing or other medical errors. The result is a healthy patient-physician relationship, which can lead to better health outcomes through appropriate use of safe and effective medicines that save lives, cure disease, and alleviate pain and suffering.

ACP favors a positive working relationship with the pharmaceutical and pharmacy industry to explore ways to provide more effective education to patients and physicians. The pharmaceutical industry plays an essential role in improving patient care by making invaluable contributions to the field of medicine as it continues to develop new life-saving therapies and provide financial support to public education programs that educate patients on how to manage their own health. Physicians would not be able to provide patients with the benefits of life-saving therapies without the availability of the thousands of medications that are available because of the pharmaceutical industry's investment in research and development. Similarly, ACP recognizes pharmacists as a key member of the health care team who help to ensure patient satisfaction, education, and safety.

ACP acknowledges the need for the pharmaceutical industry to market its products. However, under the current regulatory structure, ACP encourages

pharmaceutical companies to make more use of “help-seeking” ads. Unlike “product claim” and “reminder” ads, “help-seeking” ads educate patients about a particular health condition and advise the patient to see his/her doctor without specifying a product’s name. It is critical that “help-seeking” ads be strictly monitored and regulated by the FDA to ensure there is no implication of a product claim and that the educational purposes of the ad are not lost to commercial interests in funding such an ad (such as manufacturers of the only product in a therapeutic category).

ACP also recommends that the pharmaceutical industry make a concerted effort to direct marketing to clinicians, rather than patients, who lack the training and skills to make an informed judgment about the effectiveness of new drug products. The industry should increase efforts to educate health care professionals about new medication therapies before they are marketed to the public, to warn physicians about the questions they will be receiving from their patients before the drug is advertised, and to update health professionals on new research related to the drug after it has been advertised. Physicians should also be provided with an objective, accessible source of data on the comparative effectiveness and cost of different drugs. Similarly, objective, non-product-oriented information should be provided to better educate medical students and to promote ongoing learning for practicing physicians. All information provided to health professionals by the pharmaceutical industry should be unbiased, truthful, and complete.

Outside of DTC advertisements, the College believes there is an appropriate role for pharmaceutical companies to provide financial support for public education programs that do not promote a particular drug product. The pharmaceutical industry spends millions of dollars to support the efforts of non-profit charitable organizations, including ACP, to educate the public through unrestricted educational grants that do not promote a specific product. ACP and the ACP Foundation recently received a multimillion-dollar unrestricted educational grant from Novo Nordisk to create and disseminate educational tools and information for physicians, patients, and other members of the health care team to raise awareness and teach best practices in diabetes care. This partnership illustrates that the medical and pharmaceutical professions share the goals of high quality care— including the promotion of evidence-based medicine for care of all chronic diseases, identification of the gaps between current practice and acceptable standards of care, and recognition of physicians that demonstrably improve care of their patients.

The medical profession has a duty to assist the pharmaceutical and pharmacy industry in creating effective educational tools that provide patients with clear information and facilitate discussion of treatment options between patients and physicians. ACP will continue to seek out collaborations with the pharmaceutical and pharmacy industry to ensure that patients have access to complete and non-confusing information at all points of care.

Finally, ACP views the voluntary principles offered by the pharmaceutical industry as an important start in addressing concerns about DTC advertising. However, they are not a substitute for a strengthened and effective regulatory approach to DTC advertising. The pharmaceutical industry should continue to consider additional, more binding actions to limit the potential adverse consequences of DTC advertising while Congress and the FDA continue to work on creating a more effective regulatory structure.

## Conclusion

After completing a thorough review of DTC prescription drug advertising, the ACP believes that the practice is inappropriate. It undermines the patient-physician relationship and often leaves patients confused and misinformed about medications. Recognizing the pharmaceutical industry's right to free commercial speech and the fact that current law permits DTC advertising, the ACP makes the following recommendations:

- Congress and the FDA must expeditiously strengthen laws and regulations governing DTC advertising and the FDA must be adequately funded to expand its oversight of DTC advertising.
- The public and private sectors must continue to study the effects of DTC advertising on consumer knowledge and public health.

Both the Federal Trade Commission and the U.S. Department of Justice have concluded that DTC advertising can be a powerful tool for communicating health and wellness information to consumers that can change people's behavior.<sup>1</sup> ACP supports effective tools for educating consumers and patients about health conditions and possible treatments. However, under current regulations, ACP does not consider DTC advertisements, whose primary purpose is to promote a product, an effective communication resource for patients.

The medical community, as a whole, has an obligation to empower consumers by educating them about health conditions and possible treatments. ACP will continue to work with the federal government, the pharmaceutical industry, and the pharmacy industry to ensure that patients have access to complete, truthful, and non-confusing prescription drug information.

## Glossary

|                                   |  |
|-----------------------------------|--|
| DDMAC                             | Division of Drug Marketing, Advertising, and Communications: division of FDA responsible for reviewing prescription drug advertisements.   |
| DEA                               | Drug Enforcement Administration: a component of the U.S. Department of Justice that enforces controlled substances laws and regulations and brings to the criminal and civil justice system those involved in the illicit growing, manufacturing, or distribution of controlled substances.  |
| DOJ                               | U.S. Department of Justice: primary federal criminal investigation and enforcement agency.   |
| DSB                               | Drug Safety Oversight Board: created in 2005 by the FDA to oversee the management of drug safety issues and provide emerging information to providers and patients about the risks and benefits of medicines.  |
| DTC prescription drug advertising | Direct-to-consumer prescription drug advertising: advertising typically defined as any promotional effort by pharmaceutical companies to present prescription drug information to the general public through the lay media.  |
| FDA                               | Food and Drug Administration   |
| FFDCA                             | Federal Food, Drug, and Cosmetic Act of 1938: under which the FDA was given broad authority to consider drugs misbranded if their labeling or advertising is false or misleading in any way.   |
| FTC                               | Federal Trade Commission: independent agency reporting to Congress that seeks to protect consumers against unfair, deceptive or fraudulent practices and seeks to prevent anticompetitive mergers and other anticompetitive business practices in the marketplace.   |
| GAO                               | Government Accountability Office (formerly the Government Accounting Office): an independent and nonpartisan agency that provides Congress and executive agencies with studies of programs and expenditures of the federal government. The GAO is commonly known as the investigative arm of Congress, since it evaluates federal programs, audits federal expenditures and recommends ways to make government more effective. |
| PPI                               | Patient Package Inset: used to instruct patients about the safe use of the product in an easily understood language based on the professional labeling.  |
| PhRMA                             | Pharmaceutical Research and Manufacturers of America: represents the country's leading pharmaceutical research and biotechnology companies.  |

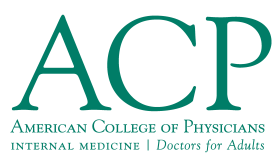


## Notes

1. Vogt D. Direct-to-Consumer Advertising of Prescription Drugs. Congressional Research Service. Library of Congress. March 25, 2005.
2. Calfee J. Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs. American Enterprise Institute; Washington, DC: July 8, 2002. Accessed at [www.ftc.gov/ogc/healthcare/calfeedtcjppm.pdf](http://www.ftc.gov/ogc/healthcare/calfeedtcjppm.pdf) on 1 February 2006.
3. IMS Health, Integrated Promotional Services TM and CMR, June 2004. Accessed at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_44304752\\_44889690,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_44304752_44889690,00.html) on 25 January 2006, as cited in Vogt D. Direct-to-Consumer Advertising of Prescription Drugs. Congressional Research Service. Library of Congress. March 25, 2005.
4. Ginsberg T. Drug firms backing off advertising after Vioxx. Philadelphia Inquirer. August 8, 2005. Accessed at [www.philly.com/mlb/philly/business/12327702.htm](http://www.philly.com/mlb/philly/business/12327702.htm) on 25 January 2006.
5. U.S. General Accountability Office, Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations. Pub. no. GAO-03-177. Washington: 2002. Accessed at [www.gao.gov/new.items/d03177.pdf](http://www.gao.gov/new.items/d03177.pdf) on 7 March 2006.
6. Aikin K, Swasy J, and Braman A. Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription drugs—Summary of FDA Survey Results. Food and Drug Administration. November 19, 2004. Accessed at [www.fda.gov/cder/ddmac/Final%20Report/FRFinalExSu1119042.pdf](http://www.fda.gov/cder/ddmac/Final%20Report/FRFinalExSu1119042.pdf) on 25 January 2006.
7. Prevention Magazine's 7th Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines, 2004.
8. "DTC Advertising: Is It Helping or Hurting?" Statement of Steven Findlay, National Institute for Health Care Management Research and Educational Foundation, before the Federal Trade Commission Health Care Workshop. September 10, 2002. Accessed at [www.ftc.gov/ogc/healthcare/findlay.pdf](http://www.ftc.gov/ogc/healthcare/findlay.pdf) on 24 January 2005.
9. Weissman J, Blumenthal D, Silk A, et al. Consumers' Reports on the Health Effects of Direct-to-Consumer Drug Advertising. Health Affairs. February 26, 2003. Accessed at [www.npcnow.org/resources/PDFs/W3-82Weissman.pdf](http://www.npcnow.org/resources/PDFs/W3-82Weissman.pdf) on 24 January 2006.
10. Prevention Magazine's 8th Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines, 2005.
11. Huang A. The Rise of Direct-to-Consumer Advertising of Prescription Drugs in the United States. JAMA. 2000;284:2240. Accessed at [jama.ama-assn.org/cgi/content/full/284/17/2240#RREF-MS1101-1-1-1](http://jama.ama-assn.org/cgi/content/full/284/17/2240#RREF-MS1101-1-1-1) on 25 January 2005.
12. FDA Guidance for Industry Consumer-Directed Broadcast Advertisements. U.S. Food and Drug Administration. August 1999. <http://www.fda.gov/cder/guidance/1804q&a.htm>.
13. Draft Guidance for Industry. Brief Summary: Disclosing Risk Information Consumer-Directed Print Advertisements. Food and Drug Administration. January 2004. Accessed at [www.fda.gov/cder/guidance/5669dft.pdf](http://www.fda.gov/cder/guidance/5669dft.pdf) on 7 March 2006.
14. Draft Guidance for Industry. "Help-Seeking" and Other Disease Awareness Communications by or on behalf of Drug and Device Firms. Food and Drug Administration. January 2004. Accessed at [www.fda.gov/cder/guidance/6019dft.pdf](http://www.fda.gov/cder/guidance/6019dft.pdf) on 7 March 2006.
15. Romza-Kutz D, Green-Kelly D. Direct-to-Consumer Prescription Drug Advertising in the United States: What is a Pharmaceutical Company to Do? Mayer, Browne, Rowe, and Maw. 2002. Accessed at [www.mayerbrown.com/BioTech/publications/kutz-kelly-scripads.pdf](http://www.mayerbrown.com/BioTech/publications/kutz-kelly-scripads.pdf) on 1 February 2006. Florida appears to prohibit DTC drug advertising, but the relevant statute is ambiguous.
16. Statement of Asa Hutchinson, Administrator, Drug Enforcement Agency, Dangers of OxyContin, Hearing Before the House Comm. on Appropriations, Subcommittee on Commerce, Justice, State, and Judiciary, 107th Cong. 2001. (cited in Romza-Kutz, Green-Kelly, Direct-to-Consumer Prescription Drug Advertising in the United States: What is a Pharmaceutical Company to Do?)
17. Statement by Dr. Sidney Wolfe, Director of Public Citizen's Health Research Group, at debate held by the National Academies of Science on August 3, 2005. As reported in: Little Evidence Ads Prompt Over-Prescribing, AEI Analyst Tells Rx Forum, But Others Differ. BNA. Aug 4, 2005.

18. 23 Drug Companies Agree to New Guidelines on Advertising. Daily Health Policy Report, Kaiser Family Foundation. August 3, 2005. Accessed at [www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=31804](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=31804) on 1 February 2006.
19. FDA Changes DTC Review Priorities in Response to New PhRMA Principles. Drug Industry Daily Online. FDA. March 6, 2006. Copy of article accessed at [nephnews.com/core/newswire.asp.html?id=692](http://nephnews.com/core/newswire.asp.html?id=692) on 20 March 2006.
20. Klein A. Nelson C. Pharmaceutical Advertising and the Learned Intermediary Defense. The Legal Intelligencer. October 17, 2005. Accessed at [www.duanemorris.com/articles/article2020.html](http://www.duanemorris.com/articles/article2020.html) on 7 March 2006.
21. Coyle S. Physician-Industry Relations. Part 1: Individual Physicians. American College of Physicians–American Society of Internal Medicine. 5 March 2002.
22. Coyle S. Physician-Industry Relations. Part 2: Organizational Issues. American College of Physicians–American Society of Internal Medicine. 5 March 2002.
23. Kravitz R, Epstein R, Feldman M, et al. Influence of Patients' Request for Direct-to-Consumer Advertised Antidepressants. JAMA. Vol. 293, No.16: April 27, 2005. Accessed at [jama.ama-assn.org/cgi/content/full/293/16/1995#RREF-JOC50019-31](http://jama.ama-assn.org/cgi/content/full/293/16/1995#RREF-JOC50019-31) on 24 January 2006.
24. Weissman J, Blumenthal D, Silk A, et al. Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising. April 28, 2004. Accessed at [content.healthaffairs.org/cgi/content/full/hlthaff.w4.219v1/DC1](http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.219v1/DC1) on 24 January 2006.
25. Pfizer Engaged in Deceptive Marketing To Promote Lipitor, Class Action Claims. BNA. September 29, 2005.
26. Waxman HA, Ensuring that Consumers Receive Appropriate Information from Drug Ads: What is the FDA's Role? Health Affairs April 28, 2004 W 4-256.
27. Jeffords J. Direct-To-Consumer Drug Advertising: You Get What You Pay For. Health Affairs web Exclusive. April 28, 2004. Accessed at [content.healthaffairs.org/cgi/content/full/hlthaff.w4.253v1/DC1](http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.253v1/DC1) on 25 January 2006.
28. U.S. Senator Bill Frist. Floor Statement on Concerns About Prescription Drug Advertising. July 1, 2005. [frist.senate.gov/index.cfm?FuseAction=Speeches.Detail&Speech\\_id=244&Month=7&Year=2005](http://frist.senate.gov/index.cfm?FuseAction=Speeches.Detail&Speech_id=244&Month=7&Year=2005)
29. U.S. Food and Drug Administration Public Hearings. Washington, D.C. Nov. 1-2, 2005.
30. Woloshin S. The Value Of Benefit Data In Direct-To-Consumer Drug Ads. Health Affairs web exclusive April 28, 2004. Accessed at [content.healthaffairs.org/cgi/reprint/hlthaff.w4.234v1](http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.234v1) on 7 March 2006.
31. Topol EJ, Failing the Public Health- Rofecoxib, Merck, and the FDA, NEJM Oct 2004;351(17): 1707-1709.
32. 65% of Promised Drug Studies Pending. Washington Post. March 4, 2006. Accessed at [www.washingtonpost.com/wp-dyn/content/article/2006/03/03/AR2006030301702\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2006/03/03/AR2006030301702_pf.html) on 20 March 2006.
33. Silber MH Chronic insomnia. NEJM 2005;353(8):803-810.
34. Lazarus D. Sleep: Can't get enough of it. San Francisco Chronicle. March 1, 2006. Accessed at [www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2006/03/01/BUGLTHFG8O50.DTL&type=business](http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2006/03/01/BUGLTHFG8O50.DTL&type=business) on 3 March 2006.
35. Krystal AD, Walsh JK, Laska E, et al. Sustained efficacy of eszopiclone over 6 months of nightly treatment: results of a randomized, double-blind, placebo-controlled study in adults with chronic insomnia. Sleep. 2003;26(7):793-799.
36. Macias W, Lewis L. Content Analysis of Direct-to-Consumer Prescription Drug Web Sites, Journal of Advertising, Winter 2003/2004. Accessed at [www.findarticles.com/p/articles/mi\\_qa3694/is\\_200301/ai\\_n9321002](http://www.findarticles.com/p/articles/mi_qa3694/is_200301/ai_n9321002) on 25 January 2006.
37. Weissman J, Blumenthal D, Silk A, et al. Consumers' Reports on the Health Effects of Direct-to-Consumer Drug Advertising. Health Affairs. February 26, 2003. Accessed at [www.npcnow.org/resources/PDFs/W3-82Weissman.pdf](http://www.npcnow.org/resources/PDFs/W3-82Weissman.pdf) on 24 January 2006.





Product #520766000