

**DIRECT-TO-CONSUMER ADVERTISING
FOR PRESCRIPTION DRUGS**

**Position Paper of the
AMERICAN COLLEGE OF PHYSICIANS
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ACP-ASIM Position Paper on
**DIRECT TO CONSUMER ADVERTISING
FOR PRESCRIPTION DRUGS**
Executive Summary

This ACP-ASIM policy statement was prepared in response to the FDA's request for comments on its current procedures regarding direct-to-consumer advertising for prescription drugs. Although the College continues to maintain that the promotion of commercial products does not constitute appropriate patient education about therapeutics, ACP-ASIM recognizes that drug advertising targeted to consumers is now here to stay, and therefore, supports strong regulations and strict guidelines to make such advertising as honest and useful as possible.

This paper presents existing policies of the American College of Physicians and the American Society of Internal Medicine and current concerns regarding DTC advertising. It provides a brief history of the FDA and its regulation of prescription drug advertising. It also contains information dealing with current practices and controversies. The pros and cons of DTC advertising are summarized, and ACP-ASIM recommendations for public policy are offered.

ACP-ASIM believes that the FDA must impose serious limits on the pharmaceutical industry to ensure that consumers receive complete and non-confusing information. The current retrospective regulatory process used by FDA is much too lenient. It allows drug companies to transmit advertising messages directly to the public before the FDA has had a chance to check the appropriateness of the information.

ACP-ASIM supports mandatory pre-release screening of all pharmaceutical advertisements. The College also favors a forum in which physicians and pharmaceutical representatives can work together to create advertisements that inform patients with clear information about specific medications and that will facilitate discussion of treatment options between patients and physicians.

DIRECT TO CONSUMER ADVERTISING FOR PRESCRIPTION DRUGS

PAST ACP-ASIM POLICIES

American College of Physicians position (as of March 13, 1984): ACP had a long-standing position supporting patients' right to know information about prescription drugs and allowing their safe and effective use. When the practice of DTC advertising began, the College issued a position paper (attached) stating that we did not favor direct-to-consumer prescription drug advertising because we believed that the promotion of commercial products does not constitute appropriate patient education about therapeutics. The College questioned the types of information that are disseminated through advertising; stressing that it is important to increase the quality of available information, not merely increasing the quantity of information. Advertising, by its nature, consists of both information and promotion. Though information may be put forth in advertisements by drug manufacturers to educate, these ads are primarily calculated to encourage increased consumption of the advertised product.

American Society of Internal Medicine position (HoD 97): ASIM opposed and sought to eliminate product-specific direct-to-consumer advertising. Failing that, ASIM urged that DTC advertising be balanced and scientifically based. ASIM opposed direct-to-consumer advertising of prescription drugs because it could result in patients receiving confusing and misleading information which could adversely affect their health.

CURRENT CONCERNS

Realizing that we are not going to reverse direct-to-consumer marketing, we need to take positive and forward-thinking positions to encourage additional guidelines that will make this advertising honest and useful; while still adhering to the original ACP and ASIM policies which opposed DTC advertising. We still strongly support the principles on which our policy is based, but realize that we need to be more proactive and realistic in dealing the with matter at hand. We believe that the FDA regulations are lacking some elementary positions, and that current guidelines provide an insufficient process with which to review the pharmaceutical industry and the products it markets directly to the public. We also believe that the rationale that the pharmaceutical companies are merely looking to educate the public is an insufficient answer.

We must question the appropriateness of advertising directly to consumers—being that advertising includes promotion in addition to information. Ideally, the “advertisements” would consist of the provision of information only and clearly would be offered in the context of public education, because we believe that promotion has no role for prescription drugs. The ads would also include a disclaimer that there are other products that will achieve the same health effects and work as well as the advertised product. The

selection of specific drugs for patients should be based upon the recommendations of physicians familiar with the illnesses of their specific patients.

We are concerned that advertising will result in increased consumption of these drugs; though their use may neither be appropriate nor necessary. Advertising is a huge industry, costing an estimated \$1.3 billion in 1998. Advertising of drug products is stimulated primarily by a profit motive and runs the risk of being quite misleading to patients. This new advertising, though not an add-on cost (the costs are redirected from other sources such as print advertising and provider advertising) may, in part, be passed on to the patient or health plan through increased pharmaceutical prices. The per member per month cost of prescription drugs for the average health plan has doubled in the past year. This increase can partially be attributed to the overall increased cost of drugs, but some of it may also reflect increased advertising costs.

The recent proliferation of drug advertising has increased the number of patients attempting to influence their own treatment regimens based on what they see on television, magazines and the Internet, rather than by what may be the best medical treatment option for them. According to reports from our members, these physicians are besieged with requests for specific products patients have seen in advertisements, which can only undermine the patient-physician relationship. Advertising also furthers the use of drugs that are not necessarily cost-effective, but are often requested by brand name. Though brand name drugs did not actually increase at a rate greater than generic drugs, the demand for these specific products increased dramatically, and prescription sales were up over 15% on the first quarter of 1998.

There are many factors that pharmaceutical companies should consider as they attempt to influence people's medication consumption. Most direct-to-consumer advertising does not warn patients of drug-drug interactions. Also, some patients are examining the lists of side effects, noting the possible complications with alarm and are stopping a much-needed medication. Often patients are not aware of the full scope of their treatments and the potential for problems exists when patients attempt to self-medicate.

However, the industry claims that direct-to-consumer advertising provides patients with the much needed information they need to take control of their own health and treatment regimens. Today's patients are much more educated and aware of their pharmaceutical options. People have access to information through medical specialty journals and the Internet. The promotion of education and patients learning about treatment options are positive aspects of modern technology. And, to give credit, the recent ads are a significant improvement over the initial advertisements for prescription medication to consumers. Although significant progress has been made in recent years, there is still room for more improvement. Problems arise when physicians end up spending time correcting misconceptions that are abundant in drug information. We recognize that increasing the discussion between physicians and their patients is a very positive circumstance, and we support initiatives that involve patients right to know, however, this time might be better spent discussing the patient's illness and treatment rather than misleading drug ads.

We must work to ensure the information patients have access to is truthful and accurate and the information does not work to destroy the patient-physician relationship. According to AMA Trustee William E. Jacott, MD, as reported in the American Medical News (February 10, 1997), physicians are increasingly feeling pressured by patients to prescribe a drug that they have seen advertised. Many times, physicians will give in to the demand and when they don't, often patients will "doctor shop" until they find a physician who will prescribe the medication. The American Academy of Family Physicians found that 71% of family physicians believed that advertising pressures doctors to use medications they may not ordinarily use, because they are requested and physicians want to keep their patients happy ("Survey Asks FPs About Direct-to-Consumer Ads, AAFP Directors' Newsletter-February 5, 1998). Balance is needed between patients playing a role in their health care and the physician's making sure that patients receive the best, and not just the most advertised, products to suit their conditions.

I. BACKGROUND

In 1906, Congress passed the Pure Food and Drug Act, making it unlawful to manufacture adulterated or misbranded foods and drugs. The Act also prohibited the shipment of such altered products in both interstate and foreign commerce. Because this Act cut across many Congressional committee jurisdictions, the powers of regulation and enforcement were uniformly distributed among the Secretaries of the Treasury, Agriculture, and Commerce. The 1906 Act deemed drugs to be adulterated when sold having a difference from the declared standards, unless the label specifically expressed this difference. Drugs are deemed misbranded when there is an imitation of another commonly used name of an accepted food or drug, or when there is a removal or a substitution of the package's contents. Other violations include a failure to state or label the quantity or the proportion of narcotics within a drug or when a false statement of curative or therapeutic effect is expressed.

The Federal Food, Drug and Cosmetic Act of 1938 established the Food and Drug Administration (FDA) to regulate food and drugs in the United States. The Act requires that manufacturers, packers, and distributors ("sponsors") who advertise prescription drugs, including biological products, disclose certain information about the advertised product's uses and risks. Advertisements must contain "information in brief summary relating to side effects, contra-indications, and effectiveness" (21 U.S.C. 352 (n)).

Though the Act does not specifically define what constitutes a prescription drug advertisement, the FDA generally interprets the term to include information (other than labeling) that is sponsored by the manufacturer and is intended to supplement or explain a product. This includes, for example, "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (202.1(1)(1)). The act and regulations specify that drugs are deemed to be misbranded if their labeling or advertising

is false or misleading in any particular way, or fails to reveal material facts (21 U.S.C. 352(a) and 321 (n) and 202.1 (e)).

However, it was not until 1962 that FDA received sole jurisdiction for regulating advertisements and other prescription drugs. Previously, authority to regulate all domestic commodities in interstate commerce was vested by Federal statute in the Federal Trade Commission. This 1962 Amendment gave the FDA authority over all aspects of prescription drugs and all promotional and advertising products related to these therapeutic pharmaceuticals.

Pharmaceutical manufacturers had, up until recently, directed their advertising to medical professionals. However, in the 1980's, marketing attention began to shift from health care professionals to the general public. Accordingly, the FDA has issued new regulations that seek to respond to differences in levels of education and understanding between physicians and the public.

II. FDA REGULATIONS FOR DIRECT-TO-CONSUMER (DTC) ADVERTISING OF PRESCRIPTION DRUGS:

The FDA has provided a list of guidelines that pharmaceutical manufacturers voluntarily adhere to in order to market their products directly to consumers in the public arena. The FDA has established multiple provisions for DTC advertising (FDA 21CFR202.1). It is important to stress that all of the requirements are predicated on the advertisement being truthful and presenting a fair balance of risks (side-effects and contra-indications) and effectiveness. If the advertisement is false or misleading, and this false information leads to a misbranding of the product, the product will be in direct violation of the Food and Drug Act. Some of the main requirements are as follows:

1. The ingredient information shall appear together without any intervening written, printed, or graphic matter
2. The order of the listing of ingredients in the advertisements shall be the same as the order of the listing of ingredients on the label of the product
3. The advertisement shall not use a fancy proprietary name of the drug or any ingredient to imply that the drug or ingredient has some unique effectiveness or composition, when, in fact, that drug or ingredient is a common substance
4. The advertisement shall not feature inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the drug's formulation
5. The advertisement may not use a proprietary that, because of spelling or pronunciation, might be confused with an established different drug or ingredient
6. The side effects and contra-indications disclosed may be limited to those pertinent to those using the drug in its' appropriate dosage and for its' recommended usage
7. Advertising requires truth in comparisons to other drugs for effectiveness measures and must use the most up-to-date and valid study information about the drug or ingredient

The prescription drug regulations distinguish between print and broadcast advertisements but require that both be written or spoken in a manner that allows the audience to understand the statements. Advertisements, in general, may not contain false or misleading claims, must provide fair balance of risks and benefits, and they must contain a brief summary of information as specified in the regulations. These components have been deemed essential parts of DTC advertisements. If an ad is missing any of these components, they are subjected to FDA enforcements (described later). Definitions of these terms are provided in Appendix A.

The specific regulations are not different depending on the target audience for the specific advertisements. The interpretation of this regulation does differ depending on whether the ad is directed towards professionals or towards the general consumer. The FDA has allowed these regulations to be subject to different interpretation outcomes because what would be considered fair balance of risk and benefit information might be different for consumers than for health care professionals.

Standard Procedure for those who violate the FDA advertising guidelines: Currently, the FDA does not have the authority to pre-screen advertising messages that drug companies plan to advertise directly to the public. The Agency has requested that these advertisements be voluntarily submitted for pre-clearance, and the Agency will then deem appropriate or send the marketing campaign back for re-tooling. The FDA can only regulate after the fact, when an advertisement is determined to be misleading or provides false evidence. Regulatory action begins with a letter requesting that the drug company pull the current misleading ads and correct claims in future promotional activities. Traditionally, companies have complied with these requests. In the case of noncompliance, the FDA can and has taken further measures. The warning letters are followed up with a request for a corrective campaign. If this request is ignored, the agency can threaten the pharmaceutical manufacturer with seizure and injunction. These voluntary consent decrees result in both a corrective campaign and the requiring of pre-clearance for all subsequent advertisements. The FDA can also require that the manufacturer send a letter of correction directly to prescribers and other parties who may have been influenced by false or misleading claims. (Kessler NEJM 1994, 1350)

Where the FDA is going: In July 1997, the FDA drafted guidelines pertaining to direct-to-consumer broadcast advertising. The draft guidance is intended to provide consumers with adequate communication of required risk information, while facilitating the process used by sponsors (drug manufacturers) to advertise their products to consumers. Within two years of publication, the FDA intends to evaluate the effects of the guidance, including effects on the public health of DTC promotion, and specifically of consumer-directed broadcast advertising.

CONTROVERSY

The emergence of many drugs that are similar to prescription drugs that are already established and on the market, can lead to price breaks for the consumer. This highly

competitive marketplace has created a marketing dream for drug manufacturers. Each drug, though it may have the same composition as others, can corner a section of the market, through selling itself in a new way to the consumer. Grabbing a section of the market can lead to great profits for the drug manufacturer; the consumer is left confused.

The pharmaceutical marketplace is enormous and allows for many similar drugs being marketed under different names. Consequently, a small percentage of the market can yield huge profits.

Positives of DTC advertising: Proponents believe that there is an educational value in direct-to-consumer advertising and this practice will improve the physician-patient relationship as it will spark conversation relating to treatment options between the two parties. It will allow consumers to have a more direct role in deciding which treatment regimens are best for them. Also, advertising directly to consumers could prompt people to seek medical care who otherwise might not be aware that they suffer from a disease for which effective treatment exists. This type of advertising might also increase patient compliance in taking medications, because people will feel they have a more direct stake in this treatment. A direct marketing benefit is that advertising increases competition, and may, therefore, lower overall drug prices.

Negatives of DTC advertising: Critics of direct-to-consumer advertising point out many of the potentially harmful effects that may result from marketing prescription drugs to patients. Opponents argue that such promotion is often misleading by failing to adequately communicate risk information. As patients learn about treatments directly, physician-patient relationships may be undermined as patients may attempt to either self-medicate, or dictate the terms of specific treatments they want, which may not be the best option. Opponents also fear that direct-to-consumer advertising may lead to excessive demands on physicians, over-medication, and drug abuse as patients demand a remedy for every symptom that ails them. These ads, because they are not written in lay-man's terms, may also confuse patients into believing that a minor difference in drugs represents a major therapeutic advance. Pharmaceutical companies will increase drug prices to recoup the costs of expensive promotional campaigns. Though proponents argue that this will reduce prices, there is no evidence that shows a reduction in drug prices at anytime.

ACP-ASIM POLICY RECOMMENDATIONS

It is important to stress the fact that ACP-ASIM still adheres to our original policy that direct-to-consumer advertising is not a proper practice. We believe that it undermines the patient-physician relationship and often leaves patients confused and misinformed about medications. However, we do recognize the reality of the situation, and since the practice has already been allowed, we suggest the strong regulation of the content of these advertisements to ensure that they are neither false nor misleading.

The current FDA guidelines and regulations are insufficient because they go into effect only after the action has occurred.

- **The 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.
- **The most reasonable approach would be a “pre-release” submission which would ensure that advertisements are clear and include such issues as a drug’s efficacy, frequency and nature of side effects, etc.**
- Ads should also be required to contain a statement declaring “This medication is not appropriate for everyone, consult your doctor about appropriateness for you”, instead of just adhering voluntarily to this request.

ACP-ASIM recognizes that often, conditions go untreated. The most noted examples of underutilized treatments include ACE inhibitors for congestive heart failure, ASA and beta-blockers after myocardial infarction, inhaled steroids in asthma and cholesterol lowering drugs in patients with high cholesterol.

- **We recognize that direct-to-consumer advertising may increase public awareness about untreated conditions, but we believe that this information could be conveyed to our patients in more effective ways such as through public service announcements and better training of physicians.** While supporters of DTC advertising point out that advertising may improve relatively low compliance among physician practices with some established treatment guidelines, we must question the appropriateness of advertising directly to consumers—being that advertising includes promotion in addition to information. There are additional concerns when DTC advertising promotes a controlled substance.

- **We believe that the pharmaceutical industry has a duty to meet with physicians to provide some truly new information about their drugs and warn physicians about the questions they will be receiving from their patients in the near future, due to an advertising campaign that is about to be launched.** ACP—ASIM is willing to work with the pharmaceutical industry to develop medically appropriate information that can be provided to consumers. In our attempt to serve as advisors and advocates for our patients, we want to take the necessary steps to ensure that our patients have appropriate information.

APPENDIX A

DEFINITIONS:

I. Requirements within drug advertisements:

Brief Summary: The Act requires that advertisements for prescription drugs for humans and animals and human biological products include information in brief summary relating to side effects, contraindications and effectiveness. The “brief summary” provision is often met by reprinting whole sections of the professional labeling, which is generally written in terms that are not easily understood by the typical consumer. The FDA recognizes that meeting the requirements of the “brief summary” is easier to accomplish in print than on television, and has made the “adequate provision” guidance in response to this difficulty.

Adequate Provision: This alternative recognizes the inability of broadcast advertisements of reasonable length to present and communicate effectively the specific information that is required to be in the “brief summary”. Advertisers are required to note the drug’s most important risk factors as part of the “major statement” and to provide “adequate provision” for the dissemination of the approved labeling to satisfy requirements mandated by the Act. (97D-9302)

Major Statement: Advertisers are required to disclose the product’s major risks in either the audio or audio and visual parts of the presentation.

II. Different types of advertisements:

“Product-Claim” Regulations require that claims of drug benefits, such as safety and efficacy, must be balanced with relevant disclosures of risks and limitations of efficacy. (202.1 (e)(5)(ii)). This balanced presentation of drug therapy is commonly referred to as “fair balance”.

“Fair Balance” In consumer-directed promotional material, the FDA requires language that is understood by consumers. Balancing information is intended to provide a framework for the consumer to understand and evaluate drug benefit claims, allowing them to form accurate opinions about prescription drugs. (95N-0227, 42582)

“Help-Seeking” ads contain information about a disease or condition and a recommendation for the consumer to consult a health care provider when appropriate; while excluding discussions of specific treatments or drugs. These ads encourage people with certain symptoms, conditions, or diseases to consult their physician to discuss general treatment options, but do not mention any specific drugs. Help-seeking ads are not legal if a certain product is the only known treatment for a disease or condition as these messages would indirectly promote the specific product. These advertisements may not contain the

name or pictorial representation of a specific drug, as the link between the product and the message will be associated by the consumer.

“Reminder” ads contain the name of the drug and other limited information, but exclude all representations or suggestions about the drug. Questions still remain about the efficacy of these types of advertisements when directed to the consumer as the patient does not have prescribing privileges and they are less likely to associate the brand name of a drug with its therapeutic functions.

III. General terms:

Prescription Drug: Therapeutic drugs available only on prescription of a licensed medical practitioner.

Advertising: Although an unofficial term, it has come to include advertisements, descriptive printed matter, all forms of labeling, oral statements, in fact any form of communication calling attention of medical and other audiences to a drug product.

Advertisements: Prescription drug advertisements subject to 502(n) of the Food Drug and Cosmetic Act include advertisements in published journals, magazines, other periodicals and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

Label: Display of written, printed, or graphic matter upon the immediate drug container as well as on the outside container or wrapper. The label must include the listing of ingredients and a complete list of each specific side effect and contraindication that may result from using the drug for its intended use. The label also includes the approved and permitted dosage for safe and effective use of the drug and adequate directions for use.

Labeling: All labels and other written, printed, or graphic material upon any article or any of its containers or wrappers, or accompanying any such article, supplied by the drug manufacturer. Labeling must contain adequate directions/information for use that is the “same language and emphasis” as the product’s approved or permitted labeling (21 U.S.C. 352(f) and 21 CFR 201.100 (d)). This requirement is generally fulfilled by including the full approved labeling for the product (the “package insert”) with the promotional materials.

Package Insert (Labeling): Labeling on or within the drug package which bears adequate information or directions for use.

Promotional Labeling: This is not specifically designated by the Act, but is governed by the regulations. These include, but are not limited to: brochures, bulletins, booklets, mailing pieces, detailing pieces, file cards, calendars, price lists, catalogs, house organs, letters (to physicians or other audiences), motion picture film strips, lantern slides, audio

tapes, other sound recordings, video tapes, exhibits, reference books distributed by the drug manufacturer, etc.
(definitions from Chadduck)

Other organizations statements on DTC advertising:

The American Association of Family Physicians (AAFP) supports efforts by manufacturers of prescription pharmaceuticals, nonprescription medications, health care devices and health-related products and services to provide general health information to the public. The AAFP believes direct-to-consumer advertising of these products and services are appropriate when the following conditions are met:

1. Advertisements must conform to applicable laws, including FDA guidelines
2. Unless already covered by applicable laws, advertisements must be labeled as such.
3. Information should be accurate, balanced, objective and complete, not false or misleading, and should not promote unhealthy or unsafe practices.
4. If specific properties or indications are mentioned, then negative or adverse reactions and effects should likewise be mentioned, in a manner that is easily accessible and understood by the consumer.
5. If advertisements direct the consumer to a physician, referral should be to the consumer's personal physician. The AAFP considers it inappropriate and unethical for an advertiser to act as a referring agent, due to the consumer's lack of awareness of any potential conflict of interest associated with such a referral.

American Association of Retired Persons (AARP) opposes policies that would add unnecessarily to the escalating costs of prescription drugs while providing no real benefits to consumers. DTC advertising could provide consumers who are enrolled in restrictive pharmacy programs with useful information that they can use in discussions with their physician. However, because the consumer is not in a position to diagnose conditions or make medical judgments about the relative safety and/or effectiveness of prescription drugs, the FDA should regulate all DTC advertising or prescription drugs in order to ensure that all information provided to the consumer in such advertising is balanced and accurate and includes information on any adverse effects.

The public advocacy group, **Public Citizen**, believes that the primary purpose of advertising is to sell drugs and the history of drug advertising indicates that ads are designed to be as misleading, and sometimes, as false as they can get away with. Patients, armed with misleading information, can greatly influence their physician's decision to prescribe a drug. Past experiences have shown that it is dangerous to rely on a voluntary approach to regulating DTC ads. FDA should be much more aggressive in insisting on prior clearance of all such ads and taking appropriate enforcement whenever serious violations occur. Public Citizen has voiced strong opposition to the FDA's new policy to open up the gates for much more TV advertising of prescription drugs, because the guidelines are relatively easier to meet than the previous regulations. PC believes that these new regulations are merely a set-up for pushing drugs with misleading information and are, therefore, irresponsible. The fact that objective comparative information is not available creates an information imbalance that makes DTC prescription drug advertisements to consumers misleading. PC does not accept that pharmaceutical

companies have the altruistic goal of educating the public and treating undiagnosed ailments. If the industry was interested in education, they would not have been instrumental in blocking FDA initiatives to provide consumers with useful written prescription drug information in the form of patient package inserts. Public Citizen is not aware of any valid scientific evidence that suggest DTC prescription drug advertising leads to better health outcomes for the public. DTC advertising may, in fact, cause needless economic hardship and perhaps serious physical harm to consumers.

Originally, the **American Medical Association (AMA)** opposed direct-to-consumer prescription drug advertising. As of 1997, they reaffirmed their opposition to product-specific advertising of prescription drugs directly to the public and added their support to FDA efforts to regulate such practices.

The American Society of Hospital Pharmacists (ASHP) supports direct-to-consumer advertising that is educational in nature about prescription drug therapies for certain medical conditions, but they oppose direct-to-consumer advertising of specific prescription drug products.

Because ASHP believes that DTC broadcast advertisements do not provide consumers with adequate risk/benefit information on prescription medicines, the Society urged the FDA to reverse its current policy on permitting DTC advertising of prescription medicines. ASHP members have observed a greater tendency toward self-diagnosis by consumers and more frequent patient requests for prescriptions for particular drugs as a result of the DTC advertising that is already taking under current FDA guidelines. There is real danger that this could lead to prescribing inappropriate medications. ASHP does not believe that the FDA proposed two-year evaluation period is an adequate safeguard against the medical errors that might arise from advertising-induced consumer-driven prescribing. The concept of enticing the public to seek prescriptions for those medicines simply cannot be reconciled with restricting the medicine's availability for public health reasons.