DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Statement of

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U.S. Food and Drug Administration

Department of Health and Human Services

"The Impact of Direct-To-Consumer Drug Advertising on Seniors' Health and Health Care Costs"

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Special Committee on Aging

United States Senate

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Rachel Behrman, Deputy Director of the Office of Medical Policy within the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency) and Director of the Cross-Centers Initiatives Task Force in the Office of the Commissioner.

Thank you for the opportunity to discuss the Agency's role and experience in oversight of direct-to-consumer (DTC) advertising. My testimony will review how FDA regulates consumer-directed advertising, the results of recent surveys the Agency has undertaken to ascertain attitudes of consumers and physicians toward this marketing activity, and future plans of the Agency to explore what issues may yet remain to be addressed by our regulation of DTC promotion.

Helping all Americans make better informed decisions concerning their health care is a top priority of the Agency. Opinion surveys conducted by FDA demonstrate that DTC advertising can encourage consumers to seek information about an illness or condition and more information about a drug from their physician or pharmacist. FDA research also demonstrated, however, that patients and physicians believe consumer-directed advertising frequently overstates the benefits of drugs and understates the risks.

Part of FDA's mission to protect the public health is to help ensure that prescription drug information is not false or misleading. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering optimal communication of labeling and promotional information to both health care professionals and to consumers.

STATUTORY AND REGULATORY AUTHORITY

FDA regulates the manufacture, sale, and distribution of drugs in the United States under authority of the Federal Food, Drug, and Cosmetic (FD&C) Act, which includes approval of prescription drug labeling that provides information about the use of a drug. Section 502(n) of the FD&C Act provides the Agency with authority to regulate prescription drug advertisements, and the implementing regulations (Title 21, *Code of Federal Regulations* [CFR] section 202.1) provide specifics about the content of such advertisements. Nothing in the law or regulations prohibits DTC promotion in any advertising medium even if the drug being advertised is a controlled substance. The advertising provisions of the FD&C Act do not address the issues of pharmaceutical coverage by insurance companies or drug product price.

Consistent with the First Amendment, FDA may only regulate prescription drug advertising that is false or misleading. To that end, FDA regulations specify, among other things, that prescription drug advertisements cannot omit material facts, and must present a "fair balance"

between benefit and risk information. Further, for print advertisements, the regulations specify that every risk addressed in the product's approved labeling also must be disclosed in the brief summary. For broadcast advertisements, however, the regulations require ads to disclose the most significant risks that appear in the labeling. The regulations further require that broadcast advertisements either contain a brief summary of "all necessary information related to side effects and contraindications" or make adequate provision for dissemination of the product's FDA-approved labeling (and the risk information it contains) in connection with the ad.

With only rare exceptions, primarily for products receiving accelerated approval, FDA cannot require that prescription drug advertisements be reviewed prior to their use. In other words, FDA's review of promotional materials is intended to occur *post hoc* – once the materials have appeared in the public domain. Thus, enforcement actions for advertising violations generally are taken *post hoc* as well. Most of FDA's enforcement actions request that sponsors stop using the violative materials. In the more egregious cases, FDA asks sponsors to run corrective advertisements or issue corrective letters to correct product misimpressions created by false or misleading, materials. Perhaps related to this, frequently sponsors voluntarily seek prior comment from FDA on draft broadcast ads for their products.

Promotional Material and Types of Advertisements

FDA regulates advertisements and other promotional material, commonly referred to as "promotional labeling," disseminated by or on behalf of the advertised product's manufacturer, packer or distributor. Mostly, this means materials that the product's sponsor disseminates or places for publication, which are directed to consumers and physicians, such as ads printed in magazines, journals and newspapers; ads broadcast over television, radio and telephone; brochures, and detailing pieces. According to the October 2002 GAO report entitled, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, "Promotion to physicians accounted for more than 80 percent of all promotional spending by pharmaceutical companies in 2001." Therefore, the bulk of the Agency's time spent reviewing promotional material, is spent reviewing materials produced for promotion to health care professionals, such as detail aids used by manufacturer representatives, convention displays, file cards, booklets, and videotapes, which are distinct from advertising directed toward consumers.

Of the three different types of ads that product sponsors use to communicate with consumers, FDA regulates two of them; "product-claim" and "reminder" ads. The third type, "help-seeking" ads are not regulated by FDA.

"Product-claim" ads are those ads which generally include both the name of a product and its use, or make a claim or representation about a prescription drug. Claims of drug benefits, such as safety and effectiveness, must be balanced with relevant disclosures of risks and limitations

of efficacy. This balanced presentation of drug therapy is commonly referred to as "fair balance." In addition, when used in print ads, sponsors must provide a brief summary of risk information included in the product's FDA-approved labeling or, for broadcast "product-claim" ads, provide convenient access to the approved labeling. In our regulations, the phrase "adequate provision" is used to identify the convenient access option.

"Reminder" ads may disclose the name of the product and certain specific descriptive information such as dosage form (i.e., tablet, capsule, or syrup) or price information, but they are not allowed to give the product's indication (use) or to make any claims or representations about the product. Reminder ads specifically are not allowed for products with serious warnings (called "black box" warnings) in their approved labeling. The regulations specifically exempt "reminder" ads from the risk disclosure requirements because historically they were designed generally to remind health care professionals of a product's availability. These ads can be confusing and frustrating to consumers – and potentially misleading – but, increasingly, we find them to be testing the limits of what might be considered a product claim. Because we believe they serve no useful purpose in the DTC arena, and have the potential to cause harm, we welcome the recent announcement from the Pharmaceutical Research and Manufacturers Association (PhRMA) that essentially supports the elimination of this type of advertisement directed at a consumer audience.

"Help-seeking" ads discuss a disease or condition and advise the audience to "see your doctor" for possible treatments. They need not include any risk information. Because no drug product is mentioned or implied, this type of ad is not considered to be a drug ad and is

not regulated by FDA, but we enthusiastically support their use and have issued draft guidance on the subject.

HOW CONSUMER-DIRECTED ADS ARE REGULATED BY FDA

Prior to the early 1980s, prescription products were not promoted directly to consumers and patients. At that time, FDA's regulation of promotional drug material was limited to that which manufacturers prepared to present to physicians and other health care professionals. In the early 1980s, a few companies began advertising products directly to patient audiences (specifically, older people concerned about pneumonia and people taking prescription ibuprofen to treat arthritis pain). Because there was no experience with promotion directed toward consumers, concerns were expressed about its possible effect on public health. The Agency and its stakeholders needed time to assess questions and concerns posed by the newly introduced DTC promotion.

To allow time to evaluate and make this assessment, FDA issued a policy statement on September 2, 1983, requesting a voluntary moratorium on DTC ads. The industry complied with the request thus giving the Agency the time needed to study whether the current regulations developed in the 1960s for prescription drug advertising directed toward health care professionals provided sufficient safeguards to protect consumers when applied to DTC promotion. This also allowed the Agency time for a dialogue among consumers, health professionals, industry, and for interested parties to conduct research on aspects of consumer-

oriented advertising. There was much discussion about DTC advertising including a 1984 symposium sponsored jointly by the University of Illinois and the Stanford Research Institute to discuss consumer-directed prescription drug advertising from a broad research and policy perspective. The voluntary moratorium remained in effect until FDA announced in the September 9, 1985, *Federal Register* (FR) Notice (50 FR 36677) its conclusion that the "current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers."

During the early 1990s, sponsors increasingly used consumer print material (magazines, etc.) to advertise their products. The ads typically included a promotional message together with the brief summary of adverse effects, similar to that used in physician-directed ads. Of note, this type of brief summary statement, which frequently appears in small print using medical jargon, is not helpful for consumers.

In the 1990s, product sponsors also started using television advertisements in a limited fashion. Television advertisements were limited because of the extensive disclosure needed to fulfill the brief summary requirement, and FDA and industry did not believe that it was feasible to disseminate the product's approved labeling in connection with the ad. There was uncertainty about how best to satisfy the risk disclosure requirements and the results typically were unsatisfactory. For example, one method would be to scroll the brief summary on the screen, which would take a minute or more at a barely readable scrolling rate. By the mid-1990s, sponsors were placing "reminder" ads on television because these ads are not required to

include a brief summary. Often these ads were confusing to consumers who were not knowledgeable about the name and use for these products.

In response to increasing consumer demand for information and clarity, FDA issued a *Federal Register* Notice on August 16, 1995, announcing a public hearing to discuss several aspects of DTC advertising and a Notice for further comment on May 14, 1996, to clarify additional issues, including the brief summary requirement. Further, in light of changes in the ability of consumers to get additional product information, FDA began to consider whether broadcast ads could be constructed to ensure access to product labeling information, the only alternative to including the brief summary requirement. FDA considered suggestions about providing access to multiple sources of product labeling as a means of satisfying the requirement that consumers have convenient access to FDA-approved labeling when manufacturers broadcast a "product-claim" ad.

In August 1997, FDA issued a draft guidance (finalized in 1999) entitled, "Guidance for Industry: Consumer-Directed Broadcast Advertisements" (see Attachment A) that clarified the Agency's interpretation of the existing regulations. The Guidance described an approach for ensuring that audiences exposed to prescription drug advertisements on television and radio have convenient access to the approved labeling of the advertised product. The proposed approach consisted of reference in the broadcast ad to four sources the consumer could use to obtain more detailed labeling information: a toll-free telephone number, a website address, a concurrently running print advertisement, and their health care professional. Following a

comment period, and detailed review and consideration of the comments, FDA issued the guidance in final form in August 1999 (64 FR 43197, also found at: *www.fda.gov/cder/guidance/1804fnl.htm*).

FDA continued to recognize that the risk information accompanying consumer advertisements was unsatisfactory and sought ways to remedy this within the existing regulatory framework. In April 2001, FDA issued draft guidance for industry entitled, "Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements." The draft guidance described how FDA did not intend to object to the use of certain FDA-approved patient labeling to fulfill the brief summary requirement for prescription drug and biological product print advertisements directed toward consumers. FDA said it would not object to the use of FDA-approved patient labeling if such labeling were reprinted in full and discussed comprehensively in consumer-friendly language the product's most serious and most common risks. FDA believed this labeling contained the information patients likely would find helpful in deciding whether to discuss with their health care provider the possible usefulness of the product for their own health care.

Based on continuing research, including the on-going efforts to modernize the product package insert, in February 2004, FDA published a notice of availability and requested public comment on three draft guidances pertaining to consumer-directed promotion of medical products. These are entitled: "Consumer-Directed Broadcast Advertising of Restricted Devices" "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" and

"Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms." These draft guidances are available on the FDA website at: *www.fda.gov/cder/ddmac/lawregs.htm#Guidances* and the public comments received are available at: *www.fdagov/ohrms/dockets*. Comments on the draft guidances, and resulting research, currently are under consideration.

OVERSIGHT

FDA's Division of Drug Marketing, Advertising and Communications (DDMAC), currently with a staff of approximately 40, are responsible for the review of drug product promotional materials. Under the post-marketing submission requirement, DDMAC received approximately 31,600 pieces of all categories of promotional material in 1999; 32,100 in 2000; 34,200 in 2001, 36,700 in 2002, 40,000 in 2003, and 52,800 in 2004. Certain materials are flagged for expedited review. These include materials that introduce newly approved products or products with new indications, which we refer to as "launch" materials. Also flagged for expedited review are TV and radio advertisements. In addition to promotional materials that are submitted at the time of initial use, DDMAC reviews complaints about promotion from competitors, health care professionals, and consumers; promotional activities in the commercial exhibit halls of scientific meetings, promotional meetings, and evolving technologies.

The total number of DTC broadcast advertisements (TV and radio) submitted to DDMAC in recent years was: 1999 – 293; 2000 – 443; 2001 – 376; 2002 – 486; 2003 – 474; and 2004 - 586. This includes both those advertisements that were proposed but not aired and those that were aired. Attachment B of this testimony shows 126 different products that have been the subjects of broadcast ads since August of 1997. Many of the products have been the subjects of multiple campaigns and many of the campaigns include different length "product-claim" commercials – variations of the initial commercial submitted to the Agency.

DDMAC does not track the number of DTC print ads. Last year, however, DDMAC estimated the consumer pieces to be about one-sixth of the total, or about 8,400. It should be noted that these are not all DTC print and broadcast ads, but also consumer promotional pieces distributed by drug companies directly to consumers or through health care providers to patients.

Many companies send new proposed DTC broadcast concepts to DDMAC for comments in advance of use, although companies are under no obligation to follow DDMAC's advice. Consequently, DDMAC generally does not see the final broadcast ad before the company submits it as part of its post-marketing requirements at the time the ad is first aired on TV or radio.

Educational Programs for Industry

DDMAC aims to increase voluntary compliance by industry through educational programs. These programs include:

- Outreach Programs: FDA staff participates in many panel discussions and presentations for groups including industry, law firms, consultants to industry, and marketing and advertising agencies. These programs are intended to increase the understanding of these groups concerning regulations relating to promotion of prescription drugs so industry can better comply.

- Website Postings: CDER posts on its website all Warning Letters and untitled letters and the cited promotional materials. Industry has noted that these letters serve as useful examples of violations that FDA has acted against and helps them understand what type of promotion is unacceptable.

- Guidances: FDA publishes guidances in areas for which industry seeks clarification. An example is the guidance on broadcast advertisement published in August 1999, following on the draft guidance published in August 1997. Guidances help industry understand FDA's current thinking and how to comply with the regulations.

- Advisory Comments: Even when not required to do so, often companies request DDMAC's review and comments on proposed materials. We

provide this service so companies can ensure that their materials are in compliance with the regulations.

ENFORCEMENT RELATED TO DTC PROMOTION

As stated previously, unless sponsors submit their draft materials for comment before use, DDMAC generally sees the materials at the same time as the public. DDMAC's options to address promotional materials that are false or misleading are:

- Untitled letters –notices of violations issued to sponsors requesting that they discontinue use of the violative materials.
- Warning Letters – issued to sponsors for more serious violations, such as those possibly posing serious health risks to the public.
- Injunctions and consent decrees.
- Referrals for criminal investigation or prosecution.
- Seizures.

FDA attempts to target resources at the violations with the greatest public health impact. Since late 2001, we instituted the policy that all Warning Letters and untitled letters that originate within FDA, including DDMAC letters, must be reviewed and cleared by the Agency's Office of the Chief Counsel (OCC) before issuance. FDA's practice for clearing

DDMAC Warning and untitled letters focuses on assuring that the letters cite the appropriate statutory and regulatory violations and are legally sustainable.

Criteria Used When Issuing an Untitled or Warning Letter

Untitled letters are used for less serious violations than Warning Letters. Violations that might receive an untitled letter may include overstating the effectiveness of the advertised drug product, suggesting a broader range of conditions than the drug was approved for, or making misleading claims because of inadequate context or lack of balancing risk information. Warning Letters address more serious violations, including serious safety or health risks or repetitive violative conduct which, if not promptly and adequately corrected, could lead to enforcement actions without further notice from FDA. Warning Letters generally request that the company disseminate a remedial message to correct the violative ad.

Since August 1997, for **broadcast** advertisements, FDA has issued:

- 53 untitled (or "Notice of Violation") letters on "product-claim" broadcast ads.
- 6 Warning Letters on broadcast ads.
- 15 untitled letters on purported reminder broadcast ads.
- 3 untitled letters on purported "help-seeking" broadcast ads.

Most of the violations cited were because the ad was misleading, e.g., the ad overstated or guaranteed the product's efficacy, expanded the indication or the patient population approved

for treatment, or minimized the risks of the product, through either inadequate presentation or omission of information.

Since August 1997, for **print** advertisements, the Agency has issued:

- 63 untitled letters that addressed DTC print ads or other promotional materials, including purported "reminder" and "help-seeking" materials.
- 6 Warning Letters: four for specific DTC print ads, one that included a DTC print ad as part of an overall misleading campaign, and one for another type of promotional piece.

Generally, the violations for "product-claim" print ads were similar to those cited above. Nearly all "reminder" ad violations were the result of representations about the product that triggered the need for full disclosure of benefits and risks. "Help-seeking" ad violations were due to a particular product being suggested in the message. FDA cannot determine how many specific advertisements serve as the denominator for assessing how many have resulted in enforcement action compared with those that have not.

FDA's DTC PROMOTION RESEARCH

A number of groups, including FDA, have been conducting research on DTC promotion to learn about its effects on consumers and physicians. As part of its commitment to examine the effect of DTC promotion on public health, FDA conducted three national telephone surveys of U.S. adults to ask their views on DTC promotion of prescription drugs and its effects on the

patient-physician relationship. The consumer surveys were conducted in the spring of 1999 and again in the spring of 2002, and one physician survey was conducted in the spring of 2002. FDA held a public meeting on September 22 and 23, 2003, to present this information and give other organizations and individuals an opportunity to present their research to FDA. The transcript of this meeting is available on the Internet at http://*www.fdagov/cder/ddmac/DTCmeeting2003.html*.

In addition, FDA currently is conducting research on the best way to present information in the brief summary, the page of medical information following a print advertisement. As mentioned earlier, reprinting the physician labeling is not helpful to consumers because of small fonts, dense presentation, and highly technical language. FDA is investigating why consumers use the brief summary, what are the best types of information to include, and what are the best formats for presenting the information.

Moreover, FDA plans to begin a number of research projects in the next year, including studies on the presentation of risk information in television DTC advertisements, the use of coupons and free offers in DTC advertising, and the interpretation of common phrases in DTC advertising.

TWO FDA CONSUMER SURVEYS ON DTC PROMOTION

In the two consumer surveys, FDA gave special attention to surveying adults who had recently visited a physician or other primary health care provider (within the last three months).

Participants were asked questions measuring the influence of DTC advertising on attitudes toward prescription drugs, health-related behavior, and on aspects of the doctor-patient relationship. The full report of the surveys is available on the Internet at: *http://www.fda.gov/cder/ddmac/researchka.htm*, and the Executive Summary is contained at Attachment C of this testimony.

The results of the two consumer surveys indicate that DTC advertising is very good at increasing awareness of products and may serve as stimulus for consumers to seek more information about their health and the drug product. Patients who asked about a specific brand of drug were more likely to be prescribed the drug they asked about, compared to patients who simply asked if treatment was available for their condition. Very few patients discuss the cost of treatment with their doctors. Many patients believe the ads overstate how well the drug works and that the ads do not present a fair balance of risk and benefit information about the product.

RESULTS OF FDA's 2002 SURVEY OF PHYSICIANS

FDA's physician survey focused on 500 office-based physicians in the U.S. who were in patient care at least half-time and included 250 primary care physicians (internists, general practitioners, family practitioners, and obstetricians/gynecologists) and 250 physicians in specialty areas targeted by DTC advertising (dermatologists, endocrinologists, allergists/pulmonologists, and psychiatrists). Participants were asked questions about the role

of DTC advertising in influencing physicians' practices and relationship with their patients. The results of the physician survey indicate that:

- Physicians believe that DTC advertising had both positive and negative effects. On the one hand, physicians feel that DTC advertising can increase patient awareness of diseases that can be treated, and prompt thoughtful discussions that result in needed treatments being prescribed. On the other hand, physicians also believe DTC advertising causes patients to think that the drug works better than it really does, that patients do not understand very well the possible risks of the advertised drug, and that DTC advertising confuses patients about the relative risks and benefits of advertised drugs.

- Physicians in this survey indicate that they are comfortable in not necessarily prescribing the advertised drug for reasons including: that a different drug was more appropriate, the drug was not right for the patient, the drug had side effects of which the patient was not aware, and/or a less expensive drug was available. A small percentage of physicians felt pressured to prescribe specific branded drugs.

- In terms of the general impression of the influence of DTC advertising on their patients and practice, responses were evenly divided amongst those who felt that DTC had a positive effect on their patients and practice, those who felt it had a negative effect and those who felt it had no effect at all.

FUTURE AGENCY ACTIVITIES CONCERNING DTC ADVERTISING

FDA is committed to ensuring that its DTC advertising policies promote truthful and non-misleading advertising that helps to better inform consumers about their health and health care choices and prevents potential misconceptions about benefits and risks of the advertised treatment.

November 1 - 2, 2005, Public Hearing On DTC Promotion

On Nov 1-2, FDA will hold a public hearing to provide an opportunity for broad public participation and comment on DTC promotion of regulated medical products, including prescription drugs for humans and animals, vaccines, blood products, and medical devices. FDA is holding this hearing because it believes the Agency, the industry, and other members of the public now have enough experience with DTC promotion to understand what regulatory issues may need to be addressed in new FDA activities. FDA particularly is interested in hearing the views of individuals and groups most affected by DTC promotion, including consumers, patients, caretakers, health professionals (physicians, physicians' assistants, dentists, nurses, pharmacists, veterinarians, and veterinarian technicians), managed care organizations, and insurers, as well as the regulated industry. Although FDA is interested in any pertinent information participants in the hearing would like to share, the Agency is seeking input on a number of specific questions, including:

- Does current DTC promotion present the benefits and risks of using medical products in an accurate, non-misleading, balanced, and understandable way?

- Could changes in certain required prescription drug disclosures – the package insert for print "promotional" labeling and the brief summary for print advertisements – improve the usefulness of this information for consumers?
- Could changes in the requirements for disclosure of certain information in broadcast advertising improve the usefulness of this information for consumers?
- As new communications technologies emerge, they create opportunities for novel approaches to DTC promotion. What issues should the Agency consider with regard to the effect of these technologies on DTC promotion?
- What action should FDA take when companies disseminate violative promotional material to consumers?

Guidance Development

In addition to ongoing guidance discussed elsewhere in this document, FDA is developing draft guidance on the presentation of risk information and plans to issue guidance in this area to industry early next year. The Agency also is conducting research to determine the purpose and optimal content and format for the brief summary in DTC ads. Upon completion and evaluation of this and other research that is being conducted by others, FDA will finalize the draft guidance "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements." FDA also is working on finalizing the draft guidance "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms" and expects to issue the final guidance early next year.

CONCLUSION

Proponents of DTC promotion argue that it has educational value and will improve the physician-patient relationship, increase patient compliance with drug therapy and physician

visits, and generally satisfy consumer interest in obtaining desired drug information. Opponents contend that consumers do not have the expertise to evaluate accurately and comprehend prescription drug advertising, that physicians will feel pressure to prescribe drugs that are not needed, and that DTC promotion will damage the physician-patient relationship and increase drug prices. The Agency believes that, if done properly, prescription drug advertising can provide consumers with important information about new prescriptions and new indications for existing prescription drugs, as well as information about symptoms of treatable illnesses and other conditions. Done properly, prescription drug advertising can assist consumers in taking a pro-active role in improving their health. However, to be of value, these advertisements must not be false or misleading. In particular, FDA remains concerned that a majority of physicians and patients surveyed believe consumer advertisements overstate efficacy and understate risk.

As a result, FDA will continue to closely monitor DTC advertising to help ensure this promotional activity is truthful and not misleading. Through our efforts including a public meeting, guidance development, research – both ours and that of others – FDA intends to examine comprehensively the current regulatory framework to ensure that it addresses appropriately the unique issues and challenges presented by consumer-directed advertising.

This concludes my remarks, Mr. Chairman. I will be glad to answer any questions you may have.

ATTACHMENT A

Guidance for Industry

Consumer-Directed Broadcast Advertisements

U.S. Department of Health and Human ServicesFood and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
August 1999

DDMAC

Guidance for Industry

Consumer-Directed Broadcast Advertisements

Additional copies of this Guidance are available from:

Office of Training and Communications Division of Communications Management Drug Information Branch, HFD-210 Center for Drug Evaluation and Research Food and Drug Administration 5600 Fishers Lane, Rockville, MD 20857 (Phone 301-827-4573) Internet: http://www.fda.gov/cder/guidance/index.htm.

or

Office of Communication, Training and Manufacturers Assistance, HFM-40 Center for Biologics Evaluation and Research Food and Drug Administration 1401 Rockville Pike, Rockville, MD 20852-1448 Internet: http://www.fda.gov/cber/guidelines.htm. Fax: 1-888-CBERFAX or 301-827-3844 Mail: the Voice Information System at 800-835-4709 or 301-827-1800

or

Communications Staff (HFV-12)
Center for Veterinary Medicine (CVM)
7500 Standish Place, Rockville, MD 20855 (Tel) 301-594-1755
http://www.fda.gov/cvm

U.S. Department of Health and Human Services Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
August 1999

DDMAC

GUIDANCE FOR INDUSTRY[1]

Consumer-Directed Broadcast Advertisements

I. INTRODUCTION

This guidance is intended to assist sponsors who are interested in advertising their prescription human and animal drugs, including biological products for humans, directly to consumers through broadcast media, such as television, radio, or telephone communications systems.[2]

II. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (the Act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, the Act requires advertisements to contain "information in brief summary relating to side effects, contraindications, and effectiveness" (21 U.S.C. 352(n)). The resulting information disclosure is commonly called the *brief summary*.

The prescription drug advertising regulations (21 CFR 202.1) distinguish between print and broadcast advertisements. Print advertisements must include the brief summary, which generally contains each of the risk concepts from the product's approved package labeling. Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the *major statement*. This guidance does not address the major statement requirement.

Sponsors of broadcast advertisements are also required to present a brief summary or, alternatively, may make "adequate provision ... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation" (21 CFR 202.1(e)(1)). This is referred to as the *adequate provision* requirement. The regulations thus specify that the major

[1] This guidance has been prepared by the Intra-Agency Group on Advertising and Promotion at the Food and Drug Administration. This guidance represents the Agency's current thinking on procedures to fulfill the requirements for disclosure of product information in connection with consumer-directed broadcast advertisements for prescription human and animal drugs, and human biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

[2] This guidance is not intended to cover the advertising of restricted medical devices, which are subject to the requirements of section 502(r) of the Federal Food, Drug, and Cosmetic Act.

statement, together with adequate provision for dissemination of the product's approved labeling, can provide the information disclosure required for broadcast advertisements.

The purpose of this guidance is to describe an approach that FDA believes can fulfill the requirement for *adequate provision* in connection with consumer-directed broadcast advertisements for prescription drug and biological products. The approach presumes that such advertisements:

- Are not false or misleading in any respect. For a prescription drug, this would include communicating that the advertised product is available only by prescription and that only a prescribing healthcare professional can decide whether the product is appropriate for a patient.
- Present a fair balance between information about effectiveness and information about risk.
- Include a thorough *major statement* conveying all of the product's most important risk information in consumer-friendly language.
- Communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.

III. FULFILLING THE *ADEQUATE PROVISION* REQUIREMENT

A sponsor wishing to use consumer-directed broadcast advertisements may meet the adequate provision requirement through an approach that will allow most of a potentially diverse audience to have reasonably convenient access to the advertised product's approved labeling. This audience will include many persons with limited access to technologically sophisticated outlets (e.g., the Internet) and persons who are uncomfortable actively requesting additional product information or are concerned about being personally identified in their search for product information. One acceptable approach to disseminating the product's approved labeling is described below. This approach includes the following components.

A. Disclosure in the advertisement of an operating toll-free telephone number for consumers to call for the approved package labeling. Upon calling, consumers should be given the choice of:

- Having the labeling mailed to them in a timely manner (e.g., within 2 business days for receipt generally within 4-6 days); or
- Having the labeling read to them over the phone (e.g., by offering consumers a selection of prerecorded labeling topics).

B. Reference in the advertisement to a mechanism to provide package

consumers with restricted access to sophisticated technology, such as the Internet, and those who are uncomfortable actively requesting additional product information or are concerned about being personally identified in their search for product information. One acceptable mechanism would be to provide the additional product information in the form of print advertisements appearing concurrently in publications that reach the exposed audience. The location of at least one of these advertisements would be referenced in the broadcast advertisement. If a print advertisement is part of an adequate provision procedure, it should supply a toll-free telephone number and an address for further consumer access to full package labeling. This mechanism of providing access to product labeling has the advantage of also providing considerable information in the form of the required brief summary and in the advertising text itself.

When a broadcast advertisement is broadly disseminated, FDA believes that ensuring that passive and privacy-sensitive information seekers have adequate access to detailed product information is critical to complying with the *adequate provision* regulatory requirement. Thus, print advertisements associated with broadly disseminated broadcast advertisements should be comparably broadly disseminated in terms of the targeted audiences.

An alternative mechanism for providing private access to product information would be to ensure the availability of sufficient numbers of brochures containing package labeling in a variety of publicly accessible sites (e.g., pharmacies, doctors' offices, grocery stores, public libraries). Brochures should be available at enough sites so that most consumers exposed to the broadcast advertisement can obtain the labeling without traveling beyond their normal range of activities. This alternative mechanism is likely to be logistically feasible only when the associated broadcast advertising campaign is relatively limited in audience reach.

C. Disclosure in the advertisement of an Internet web page (URL) address that provides access to the package labeling.

D. Disclosure in the advertisement that pharmacists, physicians (or other healthcare providers), or veterinarians (in the case of animal drugs) may provide additional product information to consumers. This statement should communicate clearly that the referenced professional is a source of additional product information.

Telephone advertisements that make a product claim (not reminder advertisements) occur when there is a telephone communication between an individual and a product's sponsor where both a product name and a representation or suggestion relating to a product (e.g., its indication) are disclosed by the sponsor. Under these circumstances, such advertisements are subject to the disclosure requirements of the Act and the regulations. However, telephone advertisements are different from advertisements broadcast through television and radio. By participating in the telephone communication, the consumer has already indicated his or her willingness to discuss the topic or receive additional information. Consequently, adequate provision for disseminating product labeling in connection with telephone advertisements may be achieved with fewer of the components listed above.

For such advertisements, adequate provision could consist of the availability of the option of having product labeling mailed to the caller in a timely manner (e.g., within 2 business days for receipt generally within 4-6 days), or having the labeling read to them over the phone (e.g., by allowing consumers to select from prerecorded labeling topics), as well as disclosing that healthcare providers are a source of additional product information.

When a broadcast advertisement is presented in a foreign language, the information sources that are part of the advertisement's "adequate provision" mechanism (i.e., print advertisements or brochures, web sites, toll-free telephone number recorded messages or operators) should be in the language of the broadcast ad. Regardless of the language used for the advertisement, current broadcast advertising regulations require the dissemination of approved product labeling, which, in most cases, must be in English, and is generally written in language directed to healthcare professionals. The Agency strongly encourages sponsors to consider the benefits of ***also*** providing consumers with nonpromotional, consumer-friendly product information in the language of the broadcast ad (e.g., FDA-approved patient labeling or accurate, consumer-friendly translations of product labeling information).

The FDA encourages sponsors who use this *adequate provision* mechanism to collect relevant data on consumer use and make their findings publicly known. FDA also encourages sponsors and other interested parties to make known their research relating to the overall effects of DTC promotion on the public health.

ATTACHMENT B:

Prescription Drug Product Ads Broadcast Directly to Consumers Since 8/97
By Drug Category
Includes Product Claim Ads and Reminder Ads
As of 8/5/05

Category	**Product**
Cholesterol/Heart Disease	Altace Crestor Lescol Lipitor Plavix Pravachol Vytorin WelChol Zocor
Osteoporosis/Menopause	Actonel Boniva Evista Femring Fosamax Premarin Prempro
Mental-Health	Buspar (persistent anxiety) Effexor XR (radio) (depression) Paxil (social or generalized anxiety disorder) Paxil CR (depression, social anxiety disorder) Prozac (depression) (infomercial) Sarafem (PMDD) Strattera (ADHD, ADD—adults only) Wellbutrin SR (depression) Wellbutrin XL (depression) Zoloft (depression, PTSD, panic disorder, social anxiety disorder)
Smoking Cessation	Nicotrol Inhaler Zyban
Diabetes	Avandia Glucophage XR (radio) Lantus

Asthma	Accolate Advair Diskus Flovent Singulair
GERD-Related Heartburn	Nexium (EE; stomach ulcer from NSAIDs) Prevacid (EE) Prilosec Protonix (EE) Omeprazole (generic)
Obesity	Meridia Xenical
STDs	Aldara (genital warts) Valtrex (genital herpes)
Arthritis	Celebrex Enbrel (rheumatoid) Humira (rheumatoid) Mobic (radio) Remicade (rheumatoid) Vioxx
Contraception	Depo-Provera NuvaRing Ortho Evra Ortho Tri-Cyclen (and acne) Ortho Tri-Cyclen Lo Plan B (radio) Seasonale Yasmin
Allergies	Allegra Clarinex Claritin Tablets Claritin Syrup (R only) Claritin D-24 (R only) Flonase Nasacort Nasacort AQ Nasonex Patanol (ocular) Rhinocort AQ Singulair Zaditor (ocular) Zyrtec

Acute Otitis Media	Omnicef (radio) Rocephin injection Zithromax oral suspension
Respiratory Tract Infections	Avelox (radio)
Influenza	Relenza Tamiflu
Overactive Bladder	Detrol Detrol LA Ditropan XL Vesicare
Migraines	Imitrex Relpax (radio) Zomig
Insomnia	Ambien Lunesta Sonata
Skin/Hair-Related	Botox Cosmetic (brow lines--temporary) (radio-R only) Denavir (cold sores) Differin (acne) Elidel (eczema) Enbrel (mod. to severe plaque psoriasis) Lamisil (nail fungus) Luxiq (scalp psoriasis/radio) MetroGel (rosacea) Ortho Tri-Cyclen (acne/contraception) Propecia (male baldness) Protopic (eczema) Retin-A Micro (acne) Valtrex (cold sores) Vaniqa (unwanted facial hair)
Erectile Dysfunction (ED)	Cialis Levitra MUSE Viagra (R only)

Other

Androgel (hypogonadism/low testosterone)

Aricept (Alzheimer's)

Avodart (benign prostate enlargement)

Celebrex (acute pain)

Cerezyme (Gaucher disease/radio)

Combivir (HIV/radio)

Covera HS (hypertension)

Diflucan (vaginal fungal infection)

Epi-Pen (anaphylaxis)

Flexeril (muscle spasm)

Flomax (benign prostatic enlargement)

Neulasta (chemo-related neutropenia)

Periostat (periodontitis aid)

Procrit (specific anemia conditions)

Quadramet (pain from certain bone cancers)

_____ Restasis (tear production for chronic dry eye)

Serevent (COPD)

Zelnorm (irritable bowel syndrome (IBS) with constipation)

Zelnorm (chronic idiopathic constipation)

ATTACHMENT C

Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs —

Summary of FDA Survey Research Results

Executive Summary
November 19, 2004

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Historically, prescription drug advertising in the United States was directed primarily toward health professionals, rather than consumers. Direct-to-consumer (DTC) prescription drug advertising, however, began to appear in print as early as the 1980s and spread increasingly to broadcast formats after the publication in 1997 of the FDA guidance for industry, *Consumer-Directed Broadcast Advertisements*.[1] As the amount and visibility of DTC promotion increased, calls for research investigating the role of DTC advertising in either creating benefits or causing problems for consumers and the healthcare system intensified. To evaluate the effects of the guidance and DTC broadcast advertising, in general, on the public health and on doctor-patient interaction, FDA conducted two surveys of patients and one survey of physicians. These surveys explored patient and physician perspectives on DTC advertising as it relates to the healthcare experience. Findings indicate that DTC advertising has important positive and negative effects. The following summary provides a brief overview of the major findings from the three surveys.

PATIENT SURVEYS

Because DTC advertising for prescription drugs targets consumers, particularly those who might have a condition the drug treats, FDA surveyed samples of adults to assess their exposure to, perceptions of, and attitudes toward DTC advertising. FDA limited the sample to consumers (patients) who had visited a healthcare provider within the last 3 months because these individuals could also provide insight on how DTC advertising influenced their relationship and interactions with their health professionals. Two national telephone surveys were conducted in 1999 (response rate: 65%; sample size = 960) and 2002 (response rate: 53%; sample size = 944). The two surveys were designed to be comparable; minor modifications were made in 2002 for clarity or general improvement.

The main objective of the patient studies was to assess the variety of ways DTC advertising could influence the doctor-patient interaction. Both the 1999 and 2002 patient surveys queried respondents about:

- Their awareness of DTC advertising
- The processes used in seeking more information and asking questions about advertised drugs
- Specific behavior in raising questions and conversing with their healthcare professional
- Their general opinions of DTC advertising

[1] FDA, guidance for industry, *Consumer-Directed Broadcast Advertisements* (August 9, 1999; 64 FR 43197; see also Appendix A.

Findings

The patient studies revealed a nearly universal awareness of DTC advertising, with 81 percent reporting exposure to broadcast or print promotion in 2002, an increase from 72 percent in 1999 (all differences reported are statistically significant at the 5 percent level). Although television was the most common vehicle of exposure, with print advertisements a close second, patient awareness of advertisements on the Internet increased from 1999 to 2002. Patients also reported substantial exposure to advertisements in grocery stores and pharmacies. Regardless of whether they understood the content, most patients knew that DTC advertisements typically contain both benefit and risk information.

Seeking Information

DTC advertisements prompted a sizable percentage of patients to seek additional information about the drug, the condition it treats, or health in general. In 2002, 43 percent of respondents reported that an advertisement caused them to look for more information, either about the drug or about their health. The ***most commonly reported sources*** of this additional information were healthcare providers. Eighty-nine percent (89%) of respondents reported obtaining information from their doctors, and 51 percent obtained information from their pharmacists. A sizable proportion of respondents also gathered information from reference books (40%) and from friends, relatives, and neighbors (38%). The number of people searching the Internet for drug or health information jumped considerably—from 18 percent in 1999 to 38 percent in 2002—with information about risks being most commonly sought.

Far more people looked for information about side effects than about benefits (61% vs. 10%). Few people spontaneously reported that they search for information about cost (4%). DTC advertisements also prompted some people to seek information about new or previously untreated conditions, although the number of people who said that a DTC advertisement caused them to talk to a doctor about such conditions decreased from 27 percent in 1999 to 18 percent in 2002.

Visits to the Healthcare Provider

• Visit prompting

Our data show that people do not report DTC advertising as a primary reason for initiating a visit to the doctor. Only 4 percent of patients said they visited their doctor because of a DTC advertisement. Instead, health-related problems, such as previous conditions and check-ups, were the most common reasons given.

• Question generation

DTC advertising and other sources did appear to play a role in generating questions for the doctor. About one third of respondents indicated that a DTC advertisement had generated a question for their doctor, similar to the number that reported friends and family members as a source of questions. Approximately 20 percent reported that a reference book sparked a question.

• Expectations about receiving prescription drugs

There have been concerns that DTC advertising has the potential to create general expectations about receiving prescriptions. Our research does not provide strong support for this concern. Approximately 42 percent of patients expected a prescription at their most recent visit with their physicians. Of these patients, the greatest percentage (63%) said this was because they expected a refill for a current prescription. Another 17 percent said that they expected a prescription because they were sick and thought or knew they had a condition that required treatment. Only 6 percent said that they expected a prescription because of an advertisement they saw on television, and 5 percent said their expectations stemmed from an advertisement in a magazine. Note that these reasons are not mutually exclusive; patients may have had more than one reason for expecting a prescription (e.g., respondents could have seen an advertisement for a drug they were currently taking).

• Asking behaviors

In both 1999 and 2002, the percentage of patients asking their doctor whether a prescription was available to treat their conditions remained constant at about 32 percent. ***Of these respondents***, 39 percent asked about a specific brand. Patients described their physicians' reactions as nearly uniformly positive when they asked about a prescription drug. Over 90 percent reported that their doctor welcomed their questions, and 83 percent reported that the doctor responded as if their questions were a normal part of the visit.

• Prescribing response

About half of the patients reported that the doctor prescribed the drug they had asked *about*. Another 41 percent of patients were told to change their behavior or diet, and about a third received a recommendation for a different prescription drug. Although all patients were equally likely to receive a recommendation to make lifestyle changes or to use over the counter (OTC) or generic drugs, patients who asked specifically about a particular brand were more likely to receive a prescription for the requested drug than those who simply asked whether there was a prescription treatment available for them.

Patient Opinions about DTC Advertising

The surveys also measured patients' opinions about various positive and negative effects of DTC advertising. Because the data are most recent, the 2002 percentages are reported in this summary, but in some cases there were substantial differences between the 1999 and 2002 data. These differences are noted below. None of the differences were moderated by demographic characteristics or health conditions.

• Information

Patient perceptions of the type, quantity, and implications of the information they glean from advertisements are important considerations when assessing the effects of DTC advertising. Generally, about three out of four respondents (77%) agreed that DTC advertisements increase awareness of new drugs (a decline from 86% in 1999). Fifty-eight percent (58%) felt the ads provide enough information to make a decision about whether to discuss the drug with a doctor (a decline from 70%). In terms of specific content within the ads, 60 percent felt the ads do not provide enough information about risks, and 44 percent believed the ads lack adequate benefit information. Finally, 39 percent of respondents thought that DTC advertisements encourage patients to look for more information about potentially serious medical conditions (this question was asked only in 2002).

• Influence on relationship with healthcare provider

Seventy-three percent (73%) of patients agreed that the ads do not minimize the role of the physician in product decisions. Forty-three percent (43%) felt the ads help them have better discussions with their doctor (a decline from 62%). Moreover, 10 percent of patients were reluctant to talk to their doctors about an advertised drug for fear of implying a distrust of the doctor (an increase from 7%).

• Overstatement of benefits

Two questions in the 2002 survey addressed the issue of accuracy in DTC advertisements, particularly with regard to claims that sponsors make. A little more than half (58%) believed the ads make the products seem better than they really are. Forty-two percent (42%) felt the advertisements make it seem like the drug will work for everyone.

• Effects on own health

Finally, patients were asked about how DTC influences their own health. Thirty-two percent (32%) felt the ads help them make better health decisions (a decline from 47%). Eighteen percent (18%) of respondents agreed that DTC advertisements remind them to take their medications, whereas 17 percent reported that the advertisements cause anxiety about their health. These last two questions were not asked in 1999.

• General attitudes

About a third of respondents (32%) indicated that they “like seeing” DTC advertisements in 2002, a substantial decline from 1999, when 52 percent reported that they "liked seeing" DTC advertisements.

Other Important Findings

- Brief summary

The *brief summary*, a section of medical information that accompanies the main display portion of all print DTC advertisements, is designed to provide detailed risk information in a publicly accessible, yet anonymous, environment. Overall, patients in the 2002 survey expressed an interest in the information provided in all parts of a print advertisement when they had a reason to consider the drug. About 78 percent of respondents reported reading all or almost all of the main body of the advertisement when interested, and 45 percent of patients reported reading all or almost all of the brief summary when they were interested in the drug. Despite this desire for information, half of those who read at least some of the brief summary described it as difficult to read.

- Cost issues

Finally, respondents in our surveys reported rarely talking to their doctor about the cost of prescription drugs. Forty percent (40%) of respondents indicated that they never discuss this issue with their healthcare provider, whereas only 16 percent reported discussing it frequently. Patients who were female, in poor health, taking one or more prescription drugs, and lacking a prescription drug insurance plan were most likely to ask their doctors about the cost of treatment.

PHYSICIAN SURVEY

The third survey, conducted in 2002, questioned office-based physicians (response rate: 46%; sample size = 500) about the role of DTC in influencing physicians' practices and relationships with their patients. The 250 primary care physicians (including internists, general practitioners, family practitioners, and obstetricians/gynecologists) and 250 specialists (including dermatologists, endocrinologists, allergists/pulmonologists, and psychiatrists) in this survey were chosen randomly from the American Medical Association's Physician Masterfile, which contains a listing of all physicians who have graduated from medical school in the United States. Specialties were selected to reflect those areas of therapy in which DTC advertising was most prominent at the time of the study.

The 2002 physician questionnaire (Appendix B) asked for information regarding the frequency of questions physicians received from patients, physicians' responses to questions regarding patient questions, and prescribing behaviors involved in a recent, specific encounter in which a DTC-advertised drug was discussed. Finally, general questions were asked about physicians' opinions regarding DTC advertising.

Findings

Physicians reported an increase in the frequency of patient questions about healthcare topics during the last 5 years in all areas except OTC drugs. The most frequently asked

questions were about drug treatments, with 85 percent of physicians reporting that their patients asked about prescription drugs frequently ("often/all the time″) and 62 percent reporting that their patients asked about generic drugs frequently. Primary care physicians were significantly more likely than specialists to report an increase in patient questions about prescription drugs.

Specific Patient Encounters

Physicians were asked to focus on a specific, recent patient encounter in which a patient had initiated discussion about a prescription drug the patient had seen advertised. Physicians were then asked to describe in their own words specific benefits and problems that arose because of this exposure.

- Benefits and problems of patient DTC exposure

Forty-one percent of physicians reported that DTC exposure led to benefits, whereas 18 percent reported that the exposure led to problems. Benefits included better discussions, greater awareness of treatments, and DTC as a source for informing and educating patients. Problems included the time needed to correct misconceptions, requests for unnecessary drugs, and requests for one prescription treatment when another treatment was effective. Overall, 73 percent of physicians indicated that their patient in this encounter asked thoughtful questions because of the DTC exposure. However, 41 percent of all physicians indicated that their patient was confused about the effectiveness of the drug because of the DTC advertisement.

- Patient drug requesting behavior

The physician survey distinguished between patients asking ***if*** there was a prescription drug to treat their problem and those asking ***for*** a particular prescription drug. Eighty-six percent (86%) of physicians recalled patients asking about a prescription drug, and 88 percent of these physicians reported that patients had the condition the drug treats. Although primary care physicians received more requests for a prescription treatment ***in general*** than did specialists (60% vs. 44%), the likelihood of prescribing the requested drug was similar (77% vs. 74%). When asked for a specific brand name drug, however, primary care physicians were both more likely to receive requests than specialists (65% vs. 52%) and also more likely to prescribe the drug (64% vs. 46%).

- Denial of requests

Physicians gave many reasons for not prescribing a requested drug. Among all physicians, the most frequently mentioned reasons were that the drug was not right for the patient and that another drug was more appropriate. Primary care physicians and specialists differed, however, in their primary reasons for not prescribing the requested drug. Primary care physicians reported not prescribing primarily because of the availability of a less expensive drug, the patient did not require a prescription drug, or the patient could engage in behavioral and diet changes. Specialists tended to decline the

request because a different drug was more appropriate, the drug was not right for the patient, or the drug had side effects unknown to the patient.

• Pressure to prescribe

About half of all physicians reported no pressure to prescribe, and 91 percent of physicians reported that the particular patient they recalled did not attempt to influence their treatment in a manner that would have been harmful to the patient. Primary care physicians did report more pressure to prescribe than did specialists, however, with 22 percent of primary care physicians feeling "somewhat" or "very pressured" to prescribe a drug, compared with 13 percent of specialists. Approximately 73 percent of primary care physicians reported that they thought patients came to the appointment expecting a prescription, whereas 63 percent of specialists felt the same way. Primary care physicians were more likely to say that this expectation influenced their decision to prescribe.

General Opinions about DTC Advertising

In addition to examining physicians' recall of recent, specific patient encounters, the study also investigated physicians' general opinions of the influence of DTC advertising on their patients and practices.

• Opinions about patient understanding

Doctors perceived differing levels of patient understanding about DTC advertised drugs. On one hand, more than 75 percent believed that their patients understood that these drugs are available only by prescription (92%), that only a doctor can make the decision about the appropriateness of the drugs (82%), and that patients understood the benefits of the drugs (78%). On the other hand, fewer than half believed that patients understood the risks and possible negative effects of the drugs (40%), the limitations of drug efficacy (30%), and the type of person who should avoid the drugs (25%).

• Opinions about problems

Physicians were also asked their perceptions of general problems arising from their patients' exposure to DTC advertising. A majority of all physicians felt that patients confuse the relative risks and benefits of DTC-advertised drugs (65%) and that these advertisements lead patients to overestimate the efficacy of the drugs (75%). Smaller percentages of physicians believed that DTC advertising causes patients to question their diagnoses (38%) and that the advertising led to tension in the doctor-patient relationship (28%). In general, primary care physicians were more likely than specialists to indicate that DTC advertising causes problems for their patients and practice.

• Opinions about benefits

With regard to general benefits of DTC advertising, 72 percent of physicians agreed that DTC advertising increases awareness of possible treatments, and 44 percent of physicians believed that it facilitates earlier awareness of health conditions. About a third of physicians thought that DTC advertising increases the likelihood of proper medication usage, and a third believed it helps patients maintain their treatment over time.

• Overall impressions

At the end of the interview, physicians were asked to give their general impressions of the influence of DTC advertising on their patients and practice. Responses were evenly divided, with about one-third each indicating that it had a positive effect, a negative effect, or no effect at all. Primary care physicians (38%) were more likely than specialists (27%) to rate the overall influence of DTC advertising as having a somewhat or very negative effect on their patients and practice.

CONCLUSIONS

The opinions and experiences of patients and physicians are critical to an evaluation of how DTC advertising affects public health. DTC advertising may potentially affect this interaction by motivating information seeking, healthcare visits, questions, and/or requests. Ultimately, such motivation can have both positive and negative effects.

The three surveys conducted by FDA found both positive and negative effects of DTC advertising on doctor-patient interaction. By and large, DTC advertising seems to increase awareness of conditions and treatments, motivate questions for the healthcare provider, and help patients ask better questions. Our data provided no evidence of increased visits as a result of DTC advertising, and few patients reported that DTC advertising motivated physician visits. On the contrary, most people reported that health reasons prompted their visits.

It is clear, however, that DTC advertising also has effects that can be troubling. Although few physicians report excessive pressure to prescribe requested drugs from patients who have seen DTC advertisements, nearly half report feeling at least a little pressure to prescribe. Both patients and doctors indicate that DTC advertisements overstate drug efficacy and do not present a fair balance of benefit and risk information. Patients gave only modest ratings to the understandability of the brief summary included in print advertisements, information that is meant to provide a more complete picture of the advertised product's risks. They also expressed some negative opinions about DTC advertising. Perhaps more important, fewer patients in the 2002 survey than in the survey conducted 3 years earlier indicated that DTC advertising was useful in terms of their interaction with their doctor and their healthcare decision making.

We continue to encourage research on all aspects of potential DTC influence on the interaction between patients and their physicians. The relationship between patients and physicians is essential for the proper dissemination of prescription drugs. Any influence that DTC advertising has on this special relationship may have broader implications for healthcare in general.