This is **Exhibit "F"** referred to in the Affidavit of **Dr. Richard Dolinar** sworn before me this 3rd day of July, 2007.

A Commissioner, etc.

CINDY TROWBRIDGE
Notary Public - Arizona
MARICOPA COUNTY
My Commission Expires
OCTOBER 5, 2007

PhRMA Guiding Principles
Direct to Consumer Advertisements About Prescription Medicines

PhRMA Guiding Principles
Direct to Consumer Advertisements
About Prescription Medicines

Preamble

Given the progress that continues to be made in society's battle against disease, patients are seeking more information about medical problems and potential treatments so they can better understand their health care options and communicate effectively with their physicians. An important benefit of direct-to-consumer (DTC) advertising is that it fosters an informed conversation about health, disease and treatments between patients and their health care practitioners.

A strong empirical record demonstrates that DTC communications about prescription medicines serve the public health by:

- Increasing awareness about diseases;
- Educating patients about treatment options;
- Motivating patients to contact their physicians and engage in a dialogue about health concerns;
- Increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated; and
- Encouraging compliance with prescription drug treatment regimens.

The Pharmaceutical Research and Manufacturers of America (PhRMA), represents America's leading pharmaceutical research and biotechnology companies. As the companies responsible for developing new and innovative medicines, PhRMA members want patients and consumers to talk to their physicians about the medicines that may help them and to fully understand the known risks regarding these medicines. We know that DTC communications, particularly DTC television advertising, can be a powerful tool for reaching and educating millions of people, and we are committed to ensuring that our DTC communications provide accurate, accessible and useful health information to patients and consumers. DTC advertising of such important and powerful products as prescription drugs should be responsibly designed to achieve these goals and to encourage the appropriate use of these products.

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First and foremost, we have a responsibility to ensure that our DTC communications comply with the regulations of the Food & Drug Administration (FDA). In general, the FDA requires all DTC information:

- To be accurate and not misleading;
- To make claims only when supported by substantial evidence;
- To reflect balance between risks and benefits; and
- To be consistent with the FDA-approved labeling.

The innovative pharmaceutical industry takes its responsibilities to comply with FDA requirements seriously. Companies devote substantial time and effort, and often ask for input from FDA, to ensure that DTC communications are accurate, fairly balanced and meet all applicable legal requirements. PhRMA member companies will engage in a dialogue with FDA to maximize opportunities for FDA review of DTC advertising prior to release, consistent with these principles and the agency's priorities and resources.

Beyond meeting their legal obligations, companies strive to deliver messages that fundamentally serve to educate patients and consumers and encourage them to seek guidance from their health care professionals.

To express the commitment of PhRMA members to deliver DTC communications that serve as valuable contributors to public health, PhRMA has established the following voluntary guiding principles.

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Guiding Principles

1. These Principles are premised on the recognition that DTC advertising of prescription medicines can benefit the public health by increasing awareness about diseases, educating patients about treatment options, motivating patients to contact their physicians and engage in a dialogue about health concerns, increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated, and encouraging compliance with prescription drug treatment regimens.

2. In accordance with FDA regulations, all DTC information should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labeling.

3. DTC television and print advertising which is designed to market a prescription drug should also be designed to responsibly educate the consumer about that medicine and, where appropriate, the condition for which it may be prescribed.

4. DTC television and print advertising of prescription drugs should clearly indicate that the medicine is a prescription drug to distinguish such advertising from other advertising for non-prescription products.

5. DTC television and print advertising should foster responsible communications between patients and health care professionals to help patients achieve better health and a more complete appreciation of both the health benefits and the known risks associated with the medicine being advertised.

6. In order to foster responsible communication between patients and health care professionals, companies should spend an appropriate amount of time to educate health professionals about a new medicine or a new therapeutic indication before commencing the first DTC advertising campaign. In determining what constitutes an appropriate time, companies should take into account the relative importance of informing patients of the availability of a new medicine, the complexity of the risk-benefit profile of that new medicine and health care professionals' knowledge of the condition being treated. Companies should continue to educate health care professionals as additional valid information about a new medicine is obtained from all reliable sources.

7. Working with the FDA, companies should continue to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious previously unknown safety risk.

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8. Companies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.

9. DTC television and print advertising should include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition.

10. DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.

11. DTC television and print advertising should be designed to achieve a balanced presentation of both the benefits and the risks associated with the advertised prescription medicine. Specifically, risks and safety information in DTC television advertising should be presented in clear, understandable language, without distraction from the content, and in a manner that supports the responsible dialogue between patients and health care professionals.

12. All DTC advertising should respect the seriousness of the health conditions and the medicine being advertised.

13. In terms of content and placement, DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved.

14. Companies are encouraged to promote health and disease awareness as part of their DTC advertising.

15. Companies are encouraged to include information in all DTC advertising, where feasible, about help for the uninsured and underinsured.

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Accountability for the Guiding Principles

Companies commit to establishing internal processes to ensure compliance with these guiding principles. Companies also commit to distributing these guidelines internally and to their advertising agencies.

Each company's intentions with regard to these guiding principles will be made public.

PhRMA will establish an office of accountability that will be responsible for receiving comments from the general public and from health care professionals regarding DTC advertising conducted by any signatory company to these principles. Any company that publicly states that it will follow the principles will be considered a signatory company.

The PhRMA office of accountability will provide to the signatory company at issue any comment that is reasonably related to compliance with the principles.

The PhRMA office of accountability will issue periodic reports to the public regarding the nature of the comments and the signatory companies' responses, and will provide a copy of each report to the FDA.

One year after the effective date of the Principles, the PhRMA office of accountability will select an independent panel of credible individuals to review reports of that year, to track the overall trends in the industry as they relate to the Principles, and to make recommendations in accordance with the Principles. The panel's report will be included in the next report of the PhRMA office of accountability.

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PhRMA Guiding Principles
Direct to Consumer Advertisements
About Prescription Medicines

Questions and Answers

Q: *What is meant by a "direct to consumer television advertisement" in the context of these principles?*

A: A direct to consumer television advertisement is a portion of television air time on broadcast or cable television that is bought by a company for the purpose of presenting information about one or more of the company's medicines. A DTC television advertisement does not include sponsorship of activities.

Q: *What is meant by "direct to consumer print advertisement" in the context of these principles?*

A: A direct to consumer print advertisement is space that is bought by a company in newspaper or magazine publications targeted to patients or consumers, or a direct mail communication paid for and disseminated by a company to patients or consumers, for the purpose of presenting information about one or more of the company's medicines. A DTC print advertisement does not include sponsorship of activities.

Q: *How long must a company wait under Principle 6 before advertising a new medicine after the medicine is approved by FDA?*

A: Principle 6 demonstrates the companies' commitment to devote sufficient resources and time to health care professional education before launching a direct to consumer advertising campaign. Principle 6 ensures that health care professionals will have a reasonable opportunity to learn about new medications before their patients ask questions about them so they will have accurate, up-to-date information to use in responding to patients' inquiries and guiding patients to the most appropriate treatment option. Establishing a single uniform waiting period for all companies and all medicines could have the unintended consequence of denying patients important information about new medicines, even after health care professionals have been well educated. Each company will decide for itself how best to implement an effective educational program, taking into account such factors as health care professionals' knowledge of the condition being treated, the severity and/or prevalence of the condition, the novelty of the new treatment, and the complexity of the medicine's risk-benefit profile and directions for use.

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Q: *Does Principle 8 require companies to do more than what is already required under current FDA regulations?*

A: Yes. Current law provides that companies must submit their DTC television advertisements to FDA upon first use for FDA's review at its discretion. Under Principle 8, while not intending to place additional burdens on FDA, companies commit to submitting new DTC television advertisements to FDA earlier than currently required and a reasonable time in advance of first use to give FDA the opportunity to comment, consistent with its priorities and resources. Companies also commit to inform FDA when they submit an advertisement of the earliest date the advertisement is scheduled to air.

Q: *Should companies notify FDA if they are specifically requesting feedback on a particular advertisement submitted under Principle 8?*

A: In order to permit FDA to allocate its resources effectively, companies should notify FDA if they are specifically requesting feedback on a submitted DTC advertisement. Companies also should indicate whether the requested FDA review is time-sensitive to help FDA prioritize its review activities. As a general matter, we understand that FDA expects companies to submit the following information with the submitted DTC advertisement: (1) a statement indicating whether the company is submitting the advertisement for prior Agency review and feedback, or for the Agency's information; and (2) if feedback is requested, a statement identifying whether the company is requesting FDA review on a priority basis; (3) a brief description of the reasons for any request for priority review (e.g., identifying the basis for the submission and the nature of any change the company deems significant) and (4) the earliest date the company plans to finalize the advertisement. Companies typically should reserve a priority review request for those submissions that are most time-sensitive, keeping in mind that FDA may choose to review only one iteration of a particular new DTC advertisement on a priority basis.

Q: *PhRMA states that, under Principle 8, companies should submit new DTC television advertisements to the FDA a reasonable time before releasing the advertisement for broadcast to give FDA the opportunity to comment, consistent with its priorities and resources. What constitutes "a reasonable time" in this context?*

A: The precise time frame for submission of a particular DTC advertisement will vary depending on the advertisement in question and purpose of the submission. If a company is specifically requesting feedback from FDA, either by priority review or standard review, it should submit the DTC advertisement far enough in advance to permit the Agency to perform the requested review. Although the timing of FDA's review of DTC advertisements will be dictated by the Agency's priorities and resources, a company seeking priority review will maximize its opportunity to receive

comments from the Agency if the company allows 30 calendar days for FDA review and comment. A company seeking non-priority review for a particular advertisement should try to allow more than 30 calendar days for FDA review, while less lead time could be appropriate if a company is submitting a particular advertisement for the Agency's information.

Q: *Does Principle 8 require companies to submit a new DTC television advertisement to FDA in advance, even if the advertisement reflects only minor changes to a previously submitted advertisement?*

A: No. Under Principle 8, companies should submit only new television advertisements or advertisements that have been changed in a way that the companies believe is significant. For instance, where a company changes an existing advertisement—possibly by changing a telephone number listed on the screen or by replacing an actor—to use for a different targeted audience, but does not substantially change the advertisement's script or theme, then the company is not required under Principle 8 to submit the changed advertisement to FDA. However, where a company changes an advertisement so that the benefit and/or risk information is presented in a different way, the company likely has made a significant change, and the advertisement should be submitted to FDA. Other circumstances that typically would trigger submission of DTC television advertisements under Principle 8 include (1) introduction of a new or never-before-advertised product; (2) new indications for existing products; (3) significant new risk information; (4) new comparative claims or patient outcome claims; or (5) new patient populations.

Q: *Does Principle 8 necessarily require a company to submit the final version of a new DTC television advertisement to FDA prior to releasing the advertisement for broadcast?*

A: No. The details of what will be submitted may be addressed in dialogue between companies and FDA.

Q: *Would additional dialogue between companies and the FDA be helpful as Principle 8 is implemented?*

A: Yes. Additional dialogue should occur to maximize opportunities for FDA review of DTC television advertising prior to release, consistent with this principle and the agency's priorities and resources.

PhRMA

Q: *Under Principles 3 and 9, does a company have to mention another medication that may also be appropriate for treating the advertised condition?*

A: No. These principles are intended to encourage companies to include in their advertisements information about therapeutic options and appropriate steps patients could take (which may or may not include other medicines), in consultation with health care professionals, to treat their disease or condition. This is consistent with the pharmaceutical industry's goal of helping patients achieve better overall health.

Q: *Is there only one right way to present risk information in advertisements?*

A: No. An advertisement will comply with Principle 11 if it presents information about the medicine's risks in a way that patients are reasonably likely to take in and understand this information. For television advertisements, the visual and audio presentation of risk information should be similar in terms of prominence and clarity to the visual and audio presentation of other information about the medicine. Of course, even the most informative advertisements can't provide information on all possible risks that may relate to each individual patient. Therefore, the conversation between a patient and a health care professional is critical to the patient's understanding of whether a medicine is right for that individual patient. DTC advertisements should motivate patients to ask their health care professionals for more information about a medicine's risks and benefits. These objectives can be achieved in a variety of ways, and each company will exercise its judgment consistent with FDA requirements.

Q: *What happens if a comment from the public about a company's DTC advertisement conflicts with recommendations or comments the company has received from FDA regarding the advertisement?*

A: The FDA has the authority to determine whether a particular advertisement is consistent with FDA regulations. If FDA chooses to give recommendations or comments on a particular DTC advertisement and the company follows those recommendations or comments, the company will be able to respond to any complaint regarding that aspect of the DTC advertisement that it complies with the PhRMA Principles by virtue of the fact that it followed FDA's recommendations.

PhRMA

Q: *Does Principle 12 suggest that all advertisements should be somber in tone and should not employ lightness, humor or entertainment?*

A: No. Principle 12 recognizes that health conditions and medical treatments are serious issues for patients. While humor or entertainment may not be appropriate in conveying all messages, they may be effective tools for attracting public attention to a particular disease or treatment, reducing any stigma associated with the condition, communicating educational messages about health conditions, and motivating patients to discuss those conditions openly with their health care providers.

Q: *What criteria should be applied to determine whether a company has complied with Principle 13 and targeted its advertising to avoid audiences that are not age appropriate for the messages in the advertisements?*

A: Advertisements containing content that may be inappropriate for children should be targeted to programs or publications that are reasonably expected to draw an audience of approximately 80 percent adults (18 years or older). Companies will be individually responsible for examining reliable, up-to-date audience composition data, to the extent that information is available, to determine whether a particular program or publication is reasonably likely to attract an audience that is age appropriate for a particular advertisement.

Revised November 2005

PhRMA

This is **Exhibit "G"** referred to in the Affidavit of **Dr. Richard Dolinar** sworn before me this 23rd day of July, 2007.

A Commissioner, etc.

CINDY TROWBRIDGE
Notary Public - Arizona
MARICOPA COUNTY
My Commission Expires
OCTOBER 5, 2007

- Exclusive
- Worldwide
- Regions
- Markets
- Economy
- Politics
- Industries
- Opinion
- Sports
- Muse
- Spend
- Audio/Video Reports
- Bloomberg Markets Magazine
- Special Report

RESOURCES

- Bloomberg TV
- Bloomberg Radio
- Bloomberg Podcasts
- Bloomberg Press

Pfizer's Celebrex TV Ads Break Mold by Stressing Risk (Update3)

By Shannon Pettypiece

April 2 (Bloomberg) -- Pfizer Inc.'s Celebrex commercials, restarted today after the adds were pulled two years ago because of the pain pill's ties to heart attacks, are breaking the rules for TV advertising, analysts and advertising experts say.

The first words heard in the ad warn that Celebrex and rivals such as ibuprofen and naproxen all may cause heart attack, stroke and death. The drug's benefits are listed afterwards, flipping the standard order for such ads. The 2 1/2 minute running time fills an entire commercial break and is five times longer than the average, an ad industry analyst said.

Pfizer ended all consumer marketing for Celebrex in December 2004, at the request of U.S. regulators. Celebrex works similarly to Merck & Co.'s Vioxx, withdrawn in 2004 after it was linked to heart attacks and strokes. Celebrex had $3.3 billion in sales in 2004, before consumer ads were stopped. Sales fell to $1.7 billion in 2005.

``It is certainly a very unusual approach," said Angela Federici, a senior vice president with Millward Brown, a marketing research firm in Fairfield, Connecticut that researches TV ads for drugmakers. ``I haven't seen that from any other brand. The length is interesting too. I haven't seen any 2 1/2 minute commercials, and I haven't worked on any."

Pfizer, the world's biggest drugmaker based in New York, revived the Celebrex ads after internal research showed 40 percent of consumers thought the drug was no longer on the market, said Steve Romano, the company's vice president of global medical, in a March 29 interview. Pfizer spent more than a year discussing the content of the ads with the U.S. Food and Drug Administration, he said.

The commercial is long because that's the time it took to fairly balance the drug's risks and benefits, Romano said.

`Interesting Strategy'

``I think it will help at the margins, but I don't think this alone will overcome the baggage that is associated with the drug to get it back to its previous stature," said Les Funtleyer, an analyst with Miller Tabak & Co. in New York, in a telephone interview today.

The first ad will run during ``The View", a daytime talk show on ABC, and will air again this evening during ABC's World News with Charles Gibson, the New York-based company said.

Pfizer said on Dec. 19, 2004, it would stop advertising Celebrex to consumers after a study showed the painkiller more than doubled the risk of heart attacks at high doses. Since then, Pfizer's stock has risen 4 percent. The company's shares rose 8 cents to $25.34 at 4 p.m. in New York Stock Exchange composite trading.

Magazines

The return to television comes after Pfizer resumed advertising in magazines in

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March, spending $36.3 million, according to media research firm Nielsen Monitor-Plus. Sales of the drug rebounded 18 percent last year to $2 billion.

While Pfizer declined to comment on how much they paid for the spots, each commercial may cost more than $200,000 to air, said Federici.

Pfizer's TV campaign two years ago featured people doing yoga and a voice urging viewers to ``celebrate Celebrex."

The latest ads only have drawings in them. After the ad lists risks linked with Celebrex, it notes benefits that include less indigestion, abdominal pain and nausea than prescription ibuprofen and naproxen. Celebrex also can be taken with low-dose aspirin, and one 200 milligram pill lasts 24 hours, the ad says.

Vioxx

NSAIDs, or non-steroidal anti-inflammatory drugs, are a family of medicines that block enzymes in the body called Cox-1 and Cox-2 that are related to the swelling and inflammation caused by arthritis. Celebrex works differently than other NSAIDs by not blocking the Cox-1 enzyme, which protects the lining of the stomach.

Concerns about Celebrex risks arose in September 2004 when Vioxx, made by Whitehouse Station, New Jersey-based Merck, was withdrawn after studies found it caused heart complications. Pfizer's similar Bextra was withdrawn in April 2005 when it was tied to a potentially fatal skin condition.

Pfizer didn't pull Celebrex from the market because it said the drug's benefits outweighed risks that could be addressed with warnings. In 2005, the FDA required that prescribing information for Celebrex and other NSAIDS carry the agency's strictest warning.

Consumer Survey

Pfizer decided to revive the Celebrex ads after internal research showed 40 percent of consumers thought the drug was no longer on the market, Romano said. The company spent more than a year discussing the content of the ads with the U.S. Food and Drug Administration, he said.

Pfizer's emphasis on the risk is part of a trend among drugmakers to make commercials more informative, said Millward Brown's Federici in a March 30 telephone interview.

By admitting to their risks upfront, drugmakers ``dial up credibility among consumers," Frederici said.

To contact the reporter on this story: Shannon Pettypiece in New York at spettypiece@bloomberg.net

Last Updated: April 2, 2007 16:18 EDT

This is **Exhibit "H"** referred to in the Affidavit of **Dr. Richard Dolinar** sworn before me this 23rd day of July, 2007.

A Commissioner, etc.

CINDY TROWBRIDGE
Notary Public - Arizona
MARICOPA COUNTY
My Commission Expires
OCTOBER 5, 2007

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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Center for Drug Evaluation and Research

EXECUTIVE SUMMARY

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

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[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.