

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION (FDA)**

**PART 15 PUBLIC HEARING
DIRECT-TO-CONSUMER (DTC) PROMOTION
OF REGULATED MEDICAL PRODUCTS
NOVEMBER 1 and 2, 2005**

COMMENTS OF THE MAGAZINE PUBLISHERS OF AMERICA (MPA)

Executive Summary

The Magazine Publishers of America, the industry association for consumer magazines, is pleased to offer these comments on direct-to-consumer (DTC) advertising of prescription drugs and medical devices to supplement the record created at the FDA public hearing on this subject held on November 1 and 2, 2005.¹ The MPA's membership includes 240 domestic and 80 international member companies publishing approximately 1,400 titles, including most major publications in the United States. Many of our members carry DTC advertising in their magazines. In addition, over 20 percent of the editorial content in the top 100 magazines is related to health issues.² DTC prescription drug advertising, especially in magazines, is of vital importance to the millions of American patients who are our readers and who turn to magazines as one of their leading sources of medical information.

In announcing the public hearing, FDA noted that DTC promotion has both proponents and opponents. The proponents, FDA said, believe that:

¹ See *Direct-to-Consumer Promotion of Regulated Medical Products; Public Hearing*, 70 Fed. Reg. 54,054 (2005).

² See *Halls Magazine Reports Co., Halls Magazine Reports February 2006*, (2006).

[DTC] 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.

The opponents, FDA said, believe that:

[C]onsumers do not have the expertise to accurately evaluate 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.

70 Fed. Reg. 54054, 54056 (September 13, 2005).

FDA invited comment on these and other issues. Based on research conducted by MPA members, the FDA, and others—as well as MPA members’ considerable experience in the field of DTC advertising, especially print, MPA believes that DTC’s proponents have far the better of the debate. As discussed in more detail below:

- DTC educates patients not only about specific drugs and medical devices but also about diseases (including those they may not realize they may have) and the availability of therapy in general. DTC is the only component of pharmaceutical marketing that is created specifically to keep consumers informed.
- DTC, especially in print, makes risk information accessible and usable. (But there is no doubt that the presentation of risk information can be improved, and we suggest some ways of doing that.)
- DTC destigmatizes conditions such as depression, opening up greater possibilities of a willingness to seek treatment for often undertreated conditions.
- DTC often prompts consultation with physicians and improves the patient-physician dialogue by giving patients both information and confidence to participate in discussions with their doctors.
- Physicians generally do not feel pressure to prescribe a particular drug when patients ask, and some of the physicians who do feel such pressure may be misinterpreting their patients’ requests.
- DTC does not raise prices. If anything, it lowers them, or allows them to rise less quickly than products which are not advertised.

As with many good things, there is always room for improvement. Thus, based on the past decade's experience with DTC advertising and magazines' perspective on effective communication strategies, we would also like to share ideas for improving DTC advertising in magazines. Responding to the FDA's question in the *Federal Register* notice regarding whether changes in the brief summary for print advertisements could improve the usefulness of this information for consumers, we offer the following recommendations:

- The DTC Brief Summary should employ easy-to-read verbiage, refrain from “medicalese,” and should be understandable by the average person. As MPA advocated in its 2003 comment to the FDA in Docket No. 2003N-0344 and as some pharmaceutical advertisers have found, it is beneficial to utilize language appropriate for a reader with an elementary school education.
- The brief summary should have a user-friendly style, with abundant “white space,” bold headings, readable font size, and a bulleted format. Several good brief summary examples employ a question and answer format.
- Risk information should be displayed prominently, using font size, style and formatting to draw readers' attention to the most significant risk information.
- Statements that consumers should consult their health care professionals if they experience any adverse side effects or have other risk factors should also be prominently displayed.

Americans need to know more about medical conditions and potential remedies and treatments as they take a more active, educated role in their own health care. We offer the following comments and data demonstrating that DTC advertising, particularly in magazines, plays an important part in educating patients and improving the quality of their health care, and their lives.

DTC Advertising, Particularly in Magazines, Plays A Vital Role in Educating Patients

As the Director of Research for the National Institute for Health Care Management (NIHCM) Research and Educational Foundation has testified before the Federal Trade Commission (FTC), “There is no doubt that DTC ads have some beneficial effect—prompting doctor visits, increasing awareness of new medications and medical conditions, and leading some patients to get drugs they need.”³

Research has shown that DTC advertising educates patients about medical conditions, treatments, and drugs. This educational component of DTC is a tremendous benefit, especially as changes in our health care system require consumers to take a more active role in managing their physical and mental health. Not only is a better-educated patient better able to participate in his/her own treatment, but research has demonstrated a secondary, but equally important, role for DTC advertising, namely informing patients about medical conditions they have of which they were unaware.

Prevention magazine, a member of MPA, has conducted numerous surveys in recent years to measure and track the effectiveness of DTC advertising. In a 2002 survey, for example, which was conducted in coordination with FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC), *Prevention* concluded, “In short, DTC advertising is effective as a means of promoting prescription medicines and

³ *Federal Trade Commission Health Care Workshop*, (2002) (statement of Steven D. Findlay, Director of Research, National Institute for Health Care Management Research and Educational Foundation), at 5.

the public health for a very simple reason: it provides consumers with the information they need in order to take control of their own health and meet their growing need to participate in the management of their own care.”⁴ In each of its annual surveys, *Prevention* has found a strong educational benefit from DTC advertising. For example, the 2005 study found that about 60 percent of consumers who were aware of the major-risk statement in print ads read the statement always or most of the time when they saw an advertisement for a medicine in which they were interested.⁵

The 2005 *Prevention* survey also showed that a significant portion of respondents reported that DTC advertisements caused them to seek treatment for previously untreated conditions.⁶ As tabulated, 78 percent of magazine readers reported that magazine DTC ads prompted them to discuss a health issue with their doctors, including 15 percent who reported that DTC advertising caused them to talk to their doctors about previously undiagnosed conditions.⁷

In addition to helping with early detection of treatable medical conditions, DTC advertising has been found to play a beneficial role in educating patients about the drugs that are available to treat a given condition. Time Inc., another MPA member, has also conducted a number of research studies on DTC advertising in recent years, including a survey conducted in conjunction with Harris Interactive in 2004. This survey found that

⁴ *Prevention, Fifth Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines, 2001-2002*, PREVENTION (2002), at 2.

⁵ *See Prevention, Consumer Reaction to Direct-to-Consumer Advertising of Prescription Medicines – Eighth Annual Survey*, (2005), at 14-15.

⁶ *See id.*

⁷ *See Prevention, supra* note 5, at 14-15, 18.

65 percent of recently diagnosed patients believed that DTC advertising provided information on who should or should not take a drug.⁸ In addition, the researchers found significant numbers of readers who reported that DTC advertising helped remind them to take their medications, a desired outcome noted by the FDA and others at the November hearing.⁹

Time Inc.'s research has also demonstrated good recall among patients regarding the information contained in DTC advertising, including important information on adverse side effects and other risks. In one of its first waves of research on DTC advertising, conducted in 2000, Time Inc. found that 73 percent of patients reported recalling adverse side effect information from DTC advertisements.¹⁰

Magazines Are An Especially Effective Medium For Disseminating DTC Prescription Drug Information

Numerous research studies have identified several key factors that distinguish magazines as a medium particularly well-suited to reach and educate consumers through DTC advertising. These factors include the engagement and involvement that magazine readers have with the content in magazines, both editorial and advertising, as well as the trust consumers feel about magazine content, including the advertising. Not surprisingly, the Time Inc./Harris Interactive survey indicated that magazines were the fourth leading

⁸ Time Inc., *DTC: Recent Sufferers—Exploring Patient Behavior from Discovery to Diagnosis*, (2004).

⁹ *See id.* at 5.

¹⁰ *Time Inc. Survey on DTC Advertising Highlights Pharmacists Role*, DRUG STORE NEWS, August 14, 2000.

source among all resources for medical information, right behind health care providers, the Internet (as a research tool), and friends or relatives.¹¹

Magazine readers have been shown to value both the advertising and editorial content of the magazines they read. In a qualitative study conducted by Starcom, a leading advertising agency, magazine readers were asked to pull out ten pages of a magazine that represented its “essence.” One third of the pages chosen were advertisements, demonstrating that readers find the advertising in magazines to be relevant and a valued part of magazine content.¹² An Engagement Factor Study conducted by Hearst Magazines, also an MPA member, reinforced Starcom’s findings. In questioning consumers about which medium’s advertising was most related to its content, the Hearst study found magazine advertising’s relevance to be two times that of the Internet and three times that of television.¹³

It is certainly not surprising that magazine readers would find DTC advertising to be relevant to the magazine’s content. Readers find quite a lot of editorial coverage of health-related topics in the pages of a magazine. For the top one hundred magazines in the country, over twenty percent of editorial content is devoted to topics that readers will find pertinent to their health and well-being, including health/medical science, general health, personal health and safety, children’s health, adult health, alternative medicine, food and nutrition, and diet.¹⁴

¹¹ Time Inc., *supra*, note 8, at 5.

¹² See Magazine Publishers of America, *Engagement: Understanding Consumers’ Relationships with Media*, (2006), at 22.

¹³ See *id.*

¹⁴ See Halls Magazine Reports Co., *supra* note 2.

In terms of overall receptivity of magazine readers to advertising, including DTC advertising, recent surveys from Roper Public Affairs and Dynamic Logic show that consumers have a positive attitude to advertising in magazines. In the Dynamic Logic study, over 60 percent of respondents were found to have a positive attitude toward the advertising content in magazines, well above television, radio and the Internet. In the Roper Public Affairs study, magazines and newspapers scored significantly better than radio, television, and the Internet when respondents were asked if advertising added to the enjoyment of the medium.¹⁵

Another characteristic of magazines that ensures that DTC advertising will succeed in educating patients is that magazine readers have been found to pay more attention compared to consumers of other media. Studies by Ball State University, BIGresearch and MindShare have all shown that print media – magazines and newspapers – are much more likely to be the sole focus of consumers as compared to radio, TV and the Internet. The Mindshare study found that 50 percent of magazine readers devote their full attention to reading a magazine, while only seven percent of television viewers and 23 percent of radio listeners gave those media their full attention. Ball State University's data show that when magazine readers do multi-task, about 80 percent of the time the magazine is receiving primary attention, way ahead of any other medium, including the Internet, newspapers, radio and television. The BIGresearch study found similar results, with print media, including magazines and newspapers, multitasked considerably less than TV, Internet, or radio.¹⁶

¹⁵ See Magazine Publishers of America, *supra* note 12, at 15.

¹⁶ See Magazine Publishers of America, *supra* note 12, at 11-12.

The magazine is also the medium that consumers trust. In three different studies, Media Choices, Neopets Youth Study, and Hearst's Engagement Factor Study, magazines were found to be the medium in which advertising is trusted the most, with Internet advertising trusted the least and broadcast media falling in between magazines and the Internet.¹⁷

DTC Advertising Enhances the Doctor-Patient Relationship and Improves Patient Care

The educational benefits of DTC carry over into improvements in patient care. DTC advertising improves patient care in two important ways. First, DTC improves the doctor-patient relationship by educating patients, thus improving their ability to communicate with their physicians. Second, as respondents in the *Prevention* survey indicated, DTC advertisements informed patients of conditions they did not know they had, and caused them to consult their doctors.

The benefits of DTC advertising in encouraging a more participatory model and increasing patient satisfaction were clearly shown in the Time Inc./Harris Interactive Study. In that 2004 survey, 74 percent of patients said DTC ads made them more confident in talking to their doctors about their conditions.¹⁸

¹⁷ See Magazine Publishers of America, *supra* note 12, at 15.

¹⁸ Time Inc., *supra*, note 8, at 5.

Some commenters at the FDA hearing argued that DTC affected the doctor-patient relationship adversely by causing patients to pressure their physicians into prescribing advertised medications. However, a new study by Rebecca Cline and Henry Young of the Barbara Ann Carmanos Cancer Institute at Wayne State University, published in the *Journal of Family Medicine*, indicates that this is simply not the case for print DTC advertisements.

The Cline and Young study found that, other than encouraging patients to initiate conversations with their physicians about advertised drugs, DTC ads did not encourage “consumers’ control.”¹⁹ Their research indicates that 55 percent of DTC advertisements cast the physician in control, while only 15 percent of the advertisements placed the patient in control.²⁰ This led the researchers to conclude that DTC “reinforces physicians’ relational control while encouraging consumers to initiate communication.”²¹

A Massachusetts General Hospital Institute for Health survey conducted in 2004, while reporting that physicians had mixed feelings about the impact of DTC advertising on their patients and practices, nevertheless found that almost 75 percent of the physicians believed that DTC advertising helped educate patients about available treatments. In addition, approximately two-thirds of the physicians said that DTC advertising improved doctor-patient dialogue.²²

¹⁹ *See Id.*

²⁰ *See id.*

²¹ *Id.*

²² *See Ben Harder, Pushing Drugs: How Medical Marketing Influences Doctors and Patients, SCIENCE NEWS, July 30, 2005; US FDA Mulls Data on the Pros and Cons of DTC Advertising, PHARMA MARKETLETTER, Sept. 24, 2003.*

In addressing a 1999 study which reported physicians feeling pressure to prescribe medications about which patients inquired or asked questions, Cline and Young noted in their study that physicians may be misinterpreting patients' questions. Citing earlier studies by Peyrot, Cooper-Patrick, and Cockbum and Pit, they concluded, "[P]hysicians often perceive 'patient demand' when patients have not specifically asked for a drug. Physicians may want to check their perceptions before acting on them, recognizing that such questions may indicate a patient's preferences for a more participatory model, which, in turn, is associated with greater patient satisfaction."²³ Thus, Cline and Young concluded that DTC advertisements "do not encourage patients to take relational control, nor do they undermine the physicians' prescribing authority."²⁴

Citing research from Fleming and Samuels, Young and Cline responded to the argument that DTC advertising hurts the doctor-patient relationship by causing patients to pressure physicians. They concluded, "Theoretically and ethically, physicians remain in control of decisions, including prescribing, by serving as learned intermediaries or 'conduits of information' between manufacturers and patients. Practically, physicians remain in control because their cooperation is necessary, even in cases where patients actively seek particular prescriptions."²⁵

²³ Cline and Young, *supra*, note 14, citing J. Cockbum and S. Pit, *Prescribing Behavior in Clinical Practice: Patients' Expectations and Doctors' Prescriptions of Patients' Expectations—a Questionnaire Study*, *BMJ*, Vol. 13, at 520-523 (1997); M. Peyrot, et al., *Direct-to-Consumer Ads Can Influence Behavior: Advertising Increases Consumer Knowledge and Prescription Drug Requests*, *MARK HEALTH SERV.*, Vol. 18, at 26-32 (1998); L. Cooper-Patrick, et al., *Race, Gender, and Partnership in the Patient-Physician Relationship*, *J. OF THE AMERICAN MED. ASS'N*, Vol. 282, at 583-589 (1999).

²⁴ Cline and Young, *supra*, note 14.

²⁵ Cline and Young, *supra*, note 14, citing D.J. Fleming and K.W. Samuels, *Direct-to-Consumer Advertising and the Learned Intermediary*, *Hosp. Practice*, Vol. 33, at 129-130 (1998).

The finding that doctors should not feel pressured to prescribe an inappropriate drug is supported by an earlier study by the National Consumers League. In 2002, the National Consumers League conducted a survey which found that only two percent of patients said they would be upset if their physicians denied their request for a particular drug.²⁶

The ability of DTC advertising to get people to the doctor and encourage them to obtain additional information about conditions, treatments, and drug remedies may be its most important benefit. In the Massachusetts General research, physicians reported that approximately 25 percent of DTC-initiated patient visits resulted in a new diagnosis.²⁷ Indeed, the FDA has concluded, “DTC advertisements prompted a sizable percentage of patients to seek additional information about the drug, the condition it treats, or health in general.”²⁸ As noted above, Time Inc.’s research indicated that a significant number of patients credited DTC with reminding them to take their medications. In addition, almost half of recent sufferers in the 2004 Time Inc. survey reported that DTC advertising encouraged them to refill their prescriptions, and a significant number reported that DTC informed them about effective dosages and durations of treatment.²⁹ A 2002-2003 study by Multimedia Audience Research Systems and published in the *International Journal of Advertising* concluded that DTC advertising had “a tangible reminder value in supporting compliance with established therapies by bringing patient ‘drop-outs’ back into the fold.”

²⁶ See PHARMA MARKETLETTER, *supra*, note 18.

²⁷ See Harper, *supra* note 13.

²⁸ Aikin, *supra* note 10, at 3.

²⁹ See Time Inc., *supra* note 8, at 5.

Their data showed that patients took the following actions in response to DTC advertising: 33 percent called for prescription refills, 39 percent made appointments with doctors, and 36 percent took medication they had been prescribed.³⁰

The DTC Brief Summary: A Vital Patient Benefit with Room for Improvement

At the November hearing, Dr. Robert Temple of the FDA stated that readability and consistency of the brief summary that accompanies DTC print advertising must be improved.³¹ FDA research has indicated that, while 78 percent of patients had read all or most of the body of DTC ads, the percentage dropped to 45 percent for the brief summary—although the 2005 *Prevention* study found that over 75 percent of readers at least skim through the brief summary.³² Some commenters at the FDA hearings advocated a more user-friendly brief summary with larger print and easier readability, including a reduction in the amount of so-called “medicalese.” MPA and its member companies support these goals and stand willing to assist advertisers in making these improvements. With the strong educational benefits the research data show that DTC provides, we believe that—with these improvements—the brief summary will be an even better educational supplement to DTC ads. We are pleased to report that progress is already being made.

³⁰ Multimedia Audience Research Systems, *Measuring the Effect of Direct-to-Consumer Communication in the World's Largest Healthcare Market*, 23 INT'L J. OF ADVERTISING, 53, 61 (2004).

³¹ *Id.*

³² Aikin, *supra*, note 12, at 5.

The self-regulatory *Guiding Principles* for DTC advertising presented by PhRMA at the November hearing call for DTC advertisements to be “presented in clear, understandable language, without distraction from the content, and in a manner that supports the reasonable dialogue between patients and health care professionals.” Furthermore, the FDA made a more consumer-friendly brief summary a cornerstone of its 2004 Draft Guidance, with the first draft guidance calling for more user-friendly information to make patients better-informed partners in their health care.³³ Together, the efforts of the FDA and industry are already producing results, as some new DTC advertisements are presenting user-friendly brief summaries.

Some of the trends that advertisers appear to be adopting include an increase in the brief summary’s “white space”, thereby highlighting key elements in the text, and more user-friendly language and less “medicalese.” Some recent advertisements have made great strides in both of these areas.

Consider, for example, recent user-friendly brief summaries contained in advertisements for Aventis’ Actonel and Allergan’s Restasis. (See attachments A and B.) Both advertisements provide ample “white space” for ease of user reading. The Actonel advertisement takes this user-friendly format a step further by presenting the brief summary in a question and answer format, starting with basic questions such as, “What is

³³ See Thompson Publishing Group Inc., *FDA Issues Three New DTC Draft Guidances*, FOOD AND DRUG REGULATION, Feb. 04, 2004, <<http://www.thompson.com/libraries/fooddrug/newsbriefs/archive/fooddrug040204b.html>>, (last visited Feb. 28, 2006).

Actonel?” The user-friendly format continues with bolded questions and bulleted answers. An important part of this format is the treatment of Actonel’s possible adverse side effects.

Some commenters at the FDA hearing in November argued that some brief summary formats bury adverse side effects in small print in cluttered text. But advertisements such as the Actonel ad provide a model for prominent treatment of risk information. For example, in bold typeface, the Actonel brief summary asks the question, “What are the possible side effects of Actonel?” In bolded, user-friendly bullets, the brief summary lists the most critical possible adverse side effects, and cautions patients—once again in bold typeface—to “Stop taking Actonel and tell your health care provider right away” if they experience any of the stated side effects. Additional possible side effects are listed in regular format. Using boldface type for the most critical conditions brings the reader’s focus to them. This brief summary format also highlights the important role of the health care provider by using bold type to convey the message that patients experiencing the conditions should stop taking the drug and contact their doctors or health care professionals.

Improved readability is important because data show that the brief summary is becoming an important source of health information for magazine readers. In 1999, Time Inc. data indicated that 31 percent of readers read the brief summary, with 69 percent responding that they had not. However, by 2005, *Prevention* magazine’s *Eighth Annual Survey of Consumer Reaction to Direct-to-Consumer Advertising of Prescription*

Medicines, conducted in coordination with Princeton Survey Associates and FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC), indicated that 75 percent of readers had reviewed the brief summary, with 23 percent reading it thoroughly, another 23 percent looking for certain key information, and 29 percent skimming through it.³⁴ Indeed, the FDA's own research reached similar conclusions on the brief summary's increased importance. In 1999, the FDA survey indicated that 59 percent of readers read at least some of the brief summary. By 2002, FDA data indicated that the figure had grown to 70 percent. In addition, the FDA data indicated that, when the reader had an interest in the drug or the condition, a full 85 percent of readers reported reading at least some of the brief summary.³⁵

DTC Advertising Does Not Raise Prices of Prescription Drugs; Concerns about DTC Content, Targeting, and Timing of Campaigns Are Being Addressed Through Self-Regulatory Initiatives

After the FDA lifted the moratorium on DTC pharmaceutical advertising in 1985,³⁶ DTC advertising increased substantially throughout the 1990's. The growth in this form of advertising was seen first in print advertisements and later in broadcast media with the promulgation of FDA's guidance regarding advertising on television and radio. As DTC advertising has grown, questions have been raised concerning the effect

³⁴ Prevention, *Consumer Reaction to Direct-to-Consumer Advertising of Prescription Medicines—Eighth Annual Survey*, (2005),

³⁵ Kathryn Aikin, Division of Drug Marketing, Advertising and Communications, Food and Drug Administration, *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship*, (2002).

³⁶ See *Direct-to-Consumer Advertising Moratorium for Prescription Drugs Ended*, 50 Fed. Reg. 366 (1985).

of the growth in DTC advertising on prescription drug prices, as well as the appropriateness of some DTC content, targeting, and timing of campaigns. Several of these questions were discussed at the November Public Hearing.

The MPA has previously submitted comments on DTC advertising to the Federal Trade Commission that included a section on research demonstrating that DTC advertising leads to lower prices, not higher prices. A copy of the MPA comments submitted to the FTC in 2002 is included as an attachment to these comments (see Attachment C). While not available in time for the MPA comments to the FTC, a study conducted by the Government Accountability Office in 2002 found similar results. The GAO study found that prices for the most heavily advertised drugs had increased 6 percent during 1999 and 2000 while prices for other drugs increased nine percent, supporting the findings of the earlier research.

With regard to questions raised about content, targeting, and timing of DTC advertising campaigns, the *Guiding Principles* for DTC advertising presented by PhRMA at the November hearing were designed in part to address advertising practices that had been deemed to cause concern among legislators, regulators, and the general public. It is expected that this self-regulatory effort will alleviate concerns in each of these areas as companies adopt the Guidelines throughout 2006.

Conclusion

The research data we have presented demonstrate that DTC advertising provides important information, educates patients, and thus, enhances the doctor-patient relationship and improves the quality of patient care. DTC advertising provides an important supplement to information physicians provide to their patients. As we have noted, DTC advertising gets patients to the doctor, helps them remember to take and refill prescriptions, and makes them better-informed participants in their own healthcare.

Magazines are an especially effective medium for DTC advertising. Readers are fully engaged with magazine content, both editorial and advertising. In addition, DTC advertising in magazines is portable. Individuals can either rip out a DTC ad with its accompanying brief summary or take the entire magazine along when consulting with a health care provider about a medical condition they may have, or showing the ad to a friend or relative that they want to help. In fact, MPA's new advertising campaign features a series of ad pages with torn edges from recognizable advertising, signifying that the advertising page that had been in the magazine was torn out by consumers who wanted to take the information contained in the ad with them. The theme of the campaign is *Ideas that Live Beyond the Page*. What a perfect description of the educational value of DTC advertising in magazines. With newer DTC advertisements that include user-friendly brief summaries, the public benefits of DTC advertising can only increase.

If your grandmother had osteoporosis,
you could too.

Fight back with Actonel.

Your grandmother's hump wasn't a slump. It was osteoporosis. Over time, with osteoporosis, multiple fractures of the spine can cause the back to curve, and in severe cases, form a hump. But Actonel helps protect your bones. It can't unslump a hump, but it can help fight fracture.

Visit Actonel.com for a free osteoporosis information kit.

Ask your doctor if Actonel is right for you.



Actonel is a prescription medication to treat and prevent postmenopausal osteoporosis. Some risk factors for osteoporosis include Caucasian or Asian race, family history, small frame or smoking.

You should not take Actonel if you have low blood calcium, have severe kidney disease, or cannot sit or stand for 30 minutes. Stop taking Actonel and tell your doctor if you experience difficult or painful swallowing, chest pain, or severe or continuing heartburn, as these may be signs of serious upper digestive problems. Side effects are generally mild or moderate and may include back or joint pain, stomach pain or upset, or constipation. Follow dosing instructions carefully.

Please see important information about Actonel on the following page.

Actonel.com
1-877-Actonel

Help fight fracture. **Actonel**
(risedronate sodium tablets)

ACTONEL® (risedronate sodium tablets)

Patient Information: ACTONEL® (AK-toh-nel) Tablets

ACTONEL (risedronate sodium tablets) 5 mg and

ACTONEL (risedronate sodium tablets) 35 mg for Osteoporosis

Read this information carefully before you start to use your medicine. Read the information you get every time you get more medicine. There may be new information. This information does not take the place of talking with your health care provider about your medical condition or your treatment. If you have any questions or are not sure about something, ask your health care provider or pharmacist.

What is the most important information I should know about ACTONEL?

ACTONEL may cause problems in your stomach and esophagus (the tube that connects the mouth and the stomach), such as trouble swallowing (dysphagia), heartburn (esophagitis) and ulcers (See "What are the Possible Side Effects of ACTONEL?").

You must follow the instructions exactly for ACTONEL to work and to lower the chance of serious side effects.

(See "How should I take ACTONEL?").

What is ACTONEL?

ACTONEL is a prescription medicine used:

- to prevent and treat osteoporosis in postmenopausal women (See "What is Osteoporosis?").
- to prevent and treat osteoporosis in men and women that is caused by treatment with steroid medicines such as prednisone.
- to treat Paget's disease of bone (osteitis deformans). The treatment for Paget's disease is very different than for osteoporosis and uses a different type of ACTONEL. This leaflet does not cover using ACTONEL for Paget's disease.

If you have Paget's disease, ask your health care provider how to use ACTONEL.

ACTONEL may reverse bone loss by stopping more loss of bone and increasing bone mass in most people who take it, even though they won't be able to see or feel a difference. ACTONEL helps lower the risk of breaking bones (fractures). Your health care provider may measure the thickness (density) of your bones or do other tests to check your progress.

See the end of this leaflet for information about osteoporosis.

Who should not take ACTONEL?

Do not take ACTONEL if you:

- have low blood calcium (hypocalcemia)
- cannot sit or stand up for 30 minutes
- have kidneys that work poorly
- have an allergy to ACTONEL. The active ingredient in ACTONEL is risedronate sodium. (See the end of this leaflet for a list of all the ingredients in ACTONEL.)

Tell your doctor before using ACTONEL if:

- you are pregnant or may become pregnant. We do not know if ACTONEL can harm your unborn child.
- you are breast-feeding or plan to breast-feed. We do not know if ACTONEL can pass through your milk and if it can harm your baby.
- you have kidney problems. ACTONEL may not be right for you.

How should I take ACTONEL?

The following instructions are for both ACTONEL 5-mg (daily) and ACTONEL 35-mg (Once-a-Week):

- Take ACTONEL first thing in the morning before you eat or drink anything except plain water.
- Take ACTONEL while you are sitting or standing up.
- Take ACTONEL with 6 to 8 ounces (about 1 cup) of plain water.
- Do **not** take it with any other drink besides plain water.
- Do not take it with coffee, tea, juice, milk, or other dairy drinks.
- Swallow ACTONEL whole. Do not chew the tablet or keep it in your mouth to melt or dissolve.
- After taking ACTONEL you must wait at least 30 minutes **BEFORE**:
 - lying down. You may sit, stand, or do normal activities like read the newspaper or take a walk
 - eating or drinking anything except plain water.
 - you take vitamins, calcium, or antacids. Take vitamins, calcium, and antacids at a different time of the day from when you take ACTONEL.
- Keep taking ACTONEL for as long as your health care provider tells you.
- For ACTONEL to treat your osteoporosis or keep you from getting osteoporosis, you have to take it as often and in the way it is prescribed.
- Your health care provider may tell you to take calcium and vitamin D supplements and to exercise.

What is my ACTONEL schedule?

If your doctor has prescribed ACTONEL 5-mg daily (a yellow tablet):

- Take 1 ACTONEL 5-mg tablet every day in the morning.
- If you forget to take your ACTONEL 5-mg in the morning, do **not** take it later in the day. Take only 1 ACTONEL 5-mg tablet the next morning and continue your usual schedule of 1 tablet a day. Do **not** take 2 tablets on the same day.

If your doctor has prescribed ACTONEL 35-mg Once-a-Week (an orange tablet):

- Choose 1 day of the week that you will remember and that best fits your schedule to take your ACTONEL 35-mg. Every week, take 1 ACTONEL 35-mg tablet in the morning on your chosen day.
- If you forget to take your ACTONEL 35-mg in the morning, do **not** take it later in the day. Take only 1 ACTONEL 35-mg tablet the next morning and continue your usual schedule of 1 tablet on your chosen day of the week. Do **not** take 2 tablets on the same day.

What should I avoid while taking ACTONEL?

- Do not eat or drink anything except water before you take ACTONEL and for at least 30 minutes after you take it.
- Do not lie down for at least 30 minutes after you take ACTONEL.
- Foods and some vitamin supplements and medicines can stop your body from absorbing (using) ACTONEL. Therefore do not take the following products at or near the time you take ACTONEL: food, milk, calcium supplements, or calcium-, aluminum- or magnesium-containing medicines, such as antacids. (See "How should I take ACTONEL?").

What are the possible side effects of ACTONEL?

Stop taking ACTONEL and tell your health care provider right away if:

- swallowing is difficult or painful
- you have chest pain
- you have very bad heartburn or it doesn't get better

ACTONEL may cause:

- pain or trouble swallowing (dysphagia)
- heartburn (esophagitis)
- ulcers in your stomach and esophagus (the tube that connects the mouth and the stomach)

For patients with osteoporosis, the overall occurrence of side effects with ACTONEL was similar to placebo (sugar pill) and most were either mild or moderate. The most common side effects with ACTONEL include back pain, joint pain, upset stomach, abdominal (stomach area) pain, constipation, diarrhea, gas, and headache. Tell your health care provider if you have pain or discomfort in your stomach or esophagus. Rarely, severe skin reactions may occur. Patients may get allergic reactions such as rash, hives, or in rare cases, swelling that can be of the face, lips, tongue, or throat, which may cause trouble breathing or swallowing.

These are not all the possible side effects of ACTONEL. You can ask your health care provider or pharmacist about other side effects. Any time you have a medical problem you think may be from ACTONEL, talk to your doctor.

What is osteoporosis?

Osteoporosis is a disease that causes bones to become thinner. Thin bones can break easily. Most people think of their bones as being solid like a rock. Actually, bone is living tissue, just like other parts of the body—your heart, brain, or skin, for example. Bone just happens to be a harder type of tissue. Bone is always changing. Your body keeps your bones strong and healthy by replacing old bone with new bone. Osteoporosis causes the body to remove more bone than it replaces. This means that bones get weaker. Weak bones are more likely to break. Osteoporosis is a bone disease that is quite common, especially in older women. However, young people and men can develop osteoporosis, too. Osteoporosis can be prevented, and with proper therapy it can be treated.

How can osteoporosis affect me?

- You may not have any pain or other symptoms when osteoporosis begins.
- You are more likely to break (fracture) a bone especially if you fall because osteoporosis makes your bones weaker. You are most likely to break a bone in your back (spine), wrist, or hip.
- You may "shrink" (get shorter).
- You may get a "hump" (curve) in your back.
- You may have bad back pain that makes you stop some activities.

Who is at risk for osteoporosis?

Many things put people at risk for osteoporosis. The following people have a higher chance of getting osteoporosis:

Women who:

- are going through or who are past menopause ("the change")
- are white (Caucasian) or Asian

People who:

- are thin
- have family members with osteoporosis
- do not get enough calcium or vitamin D
- do not exercise
- smoke
- drink alcohol often
- take bone thinning medicines (like prednisone or other corticosteroids) for a long time

General information about ACTONEL:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ACTONEL for a condition for which it was not prescribed. Do not give ACTONEL to other people, even if they have the same symptoms you have. It may harm them.

What if I have other questions about ACTONEL?

This leaflet summarizes the most important information about ACTONEL for osteoporosis. If you have more questions about ACTONEL, ask your health care provider or pharmacist. They can give you information written for health care professionals. For more information, call 1-877-ACTONEL (toll-free) or visit our web site at www.actonel.com.

What are the ingredients of ACTONEL?

ACTONEL (active ingredient): risedronate sodium.

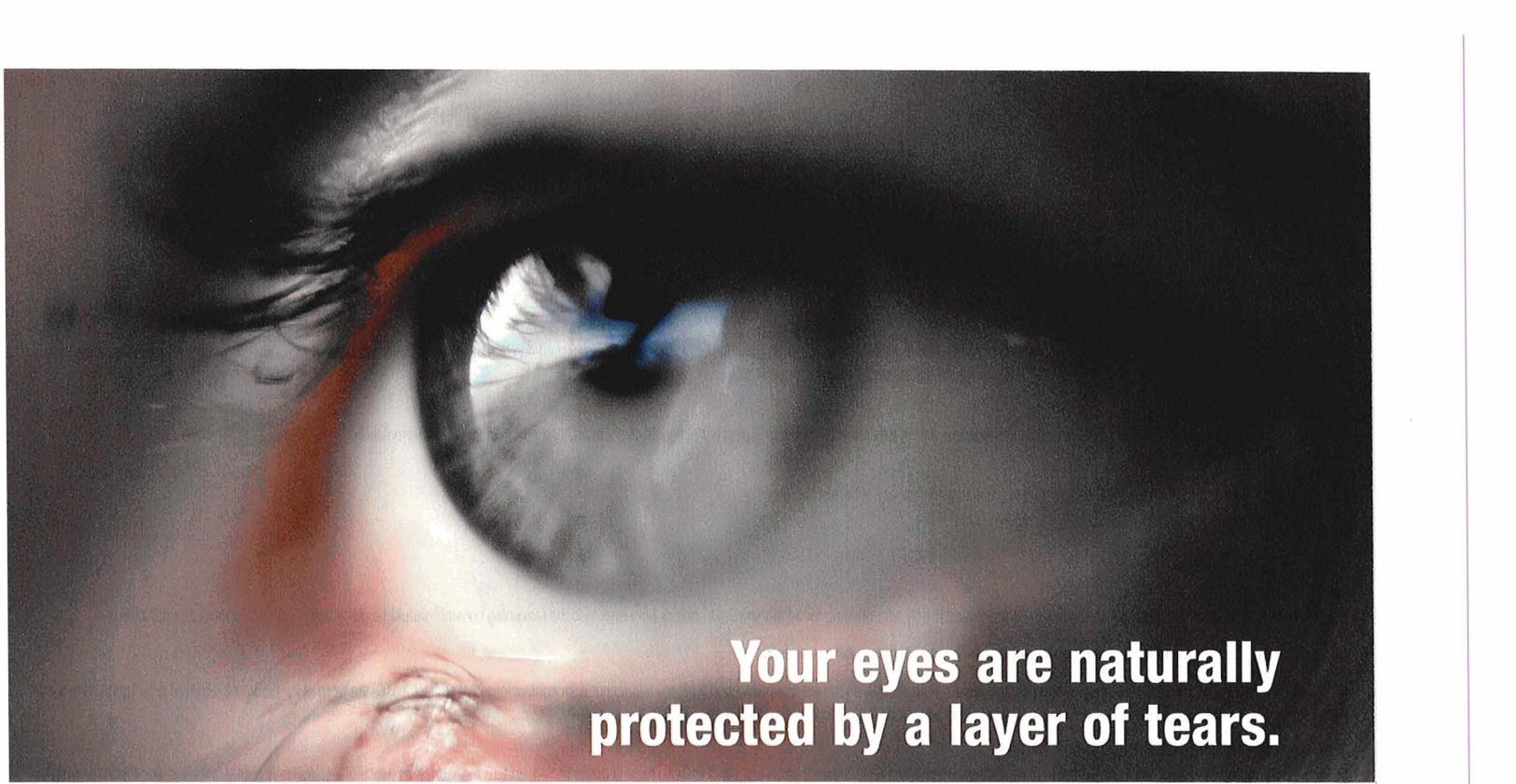
ACTONEL (inactive ingredients): croscopolone, ferric oxide red (35-mg tablets only), ferric oxide yellow, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, and titanium dioxide.

P&G
Pharmaceuticals

The Alliance for Better Bone Health

Aventis Pharmaceuticals

ACTONEL® is marketed by:
Procter & Gamble Pharmaceuticals, Inc.
Cincinnati, Ohio 45202
and
Aventis Pharmaceuticals Inc.
Kansas City, MO 64137



**Your eyes are naturally
protected by a layer of tears.**

**If you must use eye drops several times a day to make your eyes
stay comfortably moist, you may have Chronic Dry Eye.**

If you need over-the-counter eye drops to moisten your eyes, you may have Chronic Dry Eye. It's a medical condition where your eyes don't make enough tears. Artificial tears and other over-the-counter drops simply can't increase tear production.

Your eye doctor can tell you. Ask your doctor about RESTASIS®. It's the only eye drop that actually helps your eyes increase tear production with continued use.

Only an eye doctor can determine whether you have Chronic Dry Eye. That's why you should make an appointment to ask your eye doctor if RESTASIS® is right for you.

**RESTASIS®: one drop, twice a day,
with continued use,** can help you make more of your own tears.

Your own tears. Who wouldn't want that?

**To learn more, go to
www.RESTASIS72.com
or phone 1-877-447-6396
for a free information kit.**



 **Available by prescription only**
Restasis®
(Cyclosporine Ophthalmic Emulsion) 0.05%
Increases tear production with continued use

RESTASIS® helps increase your eyes' natural ability to produce tears which may be suppressed by inflammation due to Chronic Dry Eye. Increased tear production was not seen in patients using topical steroid drops or tear duct plugs.

Important Safety Information:

RESTASIS® Ophthalmic Emulsion should not be used by patients with active eye infections and has not been studied in patients with a history of herpes viral infections of the eye. The most common side effect is a burning sensation. Other side effects include eye redness, discharge, watery eyes, eye pain, foreign body sensation, itching, stinging, and blurred vision.

Please see next page for important safety information.

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Sterile, Preservative-Free

INDICATIONS AND USAGE

RESTASIS® Ophthalmic Emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

CONTRAINDICATIONS

RESTASIS® is contraindicated in patients with active ocular infections and in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

WARNING

RESTASIS® Ophthalmic Emulsion has not been studied in patients with a history of herpes keratitis.

PRECAUTIONS

General: For ophthalmic use only.

Information for Patients:

The emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

Do not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion.

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of RESTASIS® Ophthalmic Emulsion.

Carcinogenesis, Mutagenesis, and Impairment of Fertility:

Systemic carcinogenicity studies were carried out in male and female mice and rats. In the 78-week oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose males significantly exceeded the control value.

In the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control rate in the low dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose related. The low doses in mice and rats are approximately 1000 and 500 times greater, respectively, than the daily human dose of one drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Cyclosporine has not been found mutagenic/genotoxic in the Ames Test, the V79-HGPRT Test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the DNA-repair test in sperm from treated mice. A study analyzing sister chromatid exchange (SCE) induction by cyclosporine using human lymphocytes *in vitro* gave indication of a positive effect (i.e., induction of SCE).

No impairment in fertility was demonstrated in studies in male and female rats receiving oral doses of cyclosporine up to 15 mg/kg/day (approximately 15,000 times the human daily dose of 0.001 mg/kg/day) for 9 weeks (male) and 2 weeks (female) prior to mating.

Pregnancy-Teratogenic Effects:

Pregnancy category C.

Teratogenic Effects: No evidence of teratogenicity was observed in rats or rabbits receiving oral doses of cyclosporine up to 300 mg/kg/day during organogenesis. These doses in rats and rabbits are approximately 300,000 times greater than the daily human dose of one drop (28 µL) 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Non-Teratogenic Effects: Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits at 100 mg/kg/day), cyclosporine oral solution, USP, was embryo- and fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 30,000 and 100,000 times greater, respectively, than the daily human dose of one-drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryofetal toxicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 17,000 and 30,000 times greater, respectively, than the daily human dose.

Offspring of rats receiving a 45 mg/kg/day oral dose of cyclosporine from Day 15 of pregnancy until Day 21 post partum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 45,000 times greater than the daily human topical dose, 0.001 mg/kg/day, assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (15,000 times greater than the daily human dose).

There are no adequate and well-controlled studies of RESTASIS® in pregnant women. RESTASIS® should be administered to a pregnant woman only if clearly needed.

Nursing Mothers:

Cyclosporine is known to be excreted in human milk following systemic administration but excretion in human milk after topical treatment has not been investigated. Although blood concentrations are undetectable after topical administration of RESTASIS® Ophthalmic Emulsion, caution should be exercised when RESTASIS® is administered to a nursing woman.

Pediatric Use:

The safety and efficacy of RESTASIS® Ophthalmic Emulsion have not been established in pediatric patients below the age of 16.

Geriatric Use:

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

ADVERSE REACTIONS

The most common adverse event following the use of RESTASIS® was ocular burning (17%).

Other events reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Rx Only



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US PAT 4,649,047; 4,839,342; 5,474,979.

INTRODUCTION

In their Federal Register Notice which announced a workshop on “Health Care and Competition Law and Policy”¹ the Federal Trade Commission (FTC) invited written comments on any of the topics to be addressed at the workshop. According to the final agenda for the workshop², the workshop was to feature presentations as well as panel discussions. The agenda also said that at the workshop, Lesley R. Frank of the Food and Drug Administration would provide a featured presentation on “FDA Perspective on DTC Advertising and Promotion” and the fifth panel discussion would address “Advertising and Pharmaceuticals: Direct-to-Consumer Advertising and Promotion.”

These comments, filed on behalf of the Magazine Publishers of America, respond to the invitation and provide written comment showing that truthful Direct to Consumer (DTC) advertising confers large benefits on consumers and the entire society. The FTC should continue to be a strong proponent of this advertising.

BACKGROUND

Americans care about their health. This concern is reflected in health care expenditures which totaled \$1.2 trillion in 1999³ or about 13 percent of the \$9.3 trillion of Gross Domestic Product.⁴ These expenditures are projected to increase at an average rate of 7.4 percent per year for the next ten years (in nominal dollars.)⁵ Thus, as the Commission noted in the Federal Register notice announcing the workshop, “The economic significance of health care is enormous, and will become even more so in the coming years.”

Prescription drugs are an important component of health care; expenditures for them were \$100 billion in 1999⁶, or 8.9 percent of all health care expenditures. While not inconsiderable now, prescription drug expenditures will become even more important in the future as they are projected to grow at an annual rate of almost 12.8 percent (in nominal dollars) per year from 1999 at 2009, at which point they are projected to comprise almost 14 percent of health care expenditures.⁷ Thus, as the Commission might have noted in the Federal Register notice announcing the workshop, the economic significance of prescription drugs is also enormous, and will become even more so in the coming years.

Prescription drugs are promoted in a variety of ways: through advertisements in the professional literature, workshops, detailing, free samples to physicians, and directly to consumers in print and broadcast advertising. DTC advertising is, however, a relatively new phenomenon. In a letter to the *New England Journal of Medicine* in 1985 entitled “Matching

¹ accessed at <http://www.ftc.gov/os/2002/07/healthcarefrn.htm>

² accessed at <http://www.ftc.gov/opa/2002/08/hlthcarewrkshopfinalagenda.htm>

³ U.S. Census Bureau, Statistical Abstract of the United States: 2001, NO. 119. National Health Expenditures – Summary, 1960 to 1999, and Projections, 2000 to 2010.

⁴ U.S. Census Bureau, Statistical Abstract of the United States: 2001, NO. 640. Gross Domestic Product in Current and Real (1996) Dollars: 1960 to 2000.

⁵ Op. Cit. 3 and calculated from entries in it.

⁶ Op. Cit. 3

⁷ Op. Cit. 3 and calculated from entries in it.

Prescription Drugs and Consumers, The Benefits of Direct Advertising”, Alison Masson and Paul H. Rubin, then both of the Bureau of Economics of the Federal Trade Commission, noted “Prescription drugs are seldom advertised directly to consumers, partly because of strict regulation by the Food and Drug Administration. In fact, there has been a moratorium on direct consumer advertising since 1983.” The FDA lifted the moratorium in 1985⁸ and, in 1997, issued draft guidelines for broadcast advertising.⁹ DTC advertising grew rapidly thereafter, from \$791 million in 1996 to \$2.467 billion in 2000 or almost 33 percent per year.¹⁰ In 2000, it comprised 15.7 percent of all drug promotion expenditures up from 8.6 percent in 1996.¹¹

While complex interactions among consumers, their health care providers, and the organizations that provide consumers with health insurance influence many health care and pharmaceutical decisions and while firms determine the size of their DTC advertising expenditures, public policy also plays a critical role in determining both the performance and the size of the entire health care system. Thus, as the Commission noted,

It is exceedingly important that competition law and policy support and encourage efficient delivery of health care products and services. Competition law and policy should also encourage innovation in the form of new and improved drugs, treatments, and delivery options... Consumer/patient welfare is maximized by a health care system that efficiently delivers to Americans the services they desire.¹²

As these comments will show, DTC advertising provides many important benefits to consumers in their health care decisions and helps the system deliver to Americans the services they desire. Because of this, it is also exceedingly important that competition law and policy also support and encourage truthful DTC advertising.

Although DTC advertising has proponents, it is not without its detractors. Critics of it raise numerous allegations; among the most important of which are that it inflates prices of drugs, leads to their overuse, and undercuts the relationship of the doctor to the patient. As these comments show, however, these allegations are unfounded or wrongly focused. And the benefits of DTC advertising likely outweigh any possible costs.

TRUTHFUL ADVERTISING IS CRITICAL TO EFFICIENT MARKETS

Markets allocate resources efficiently only if there is sufficient information for consumers to make informed decisions. But producing and then targeting and disseminating information to the appropriate audience costs money. Consumers also devote significant resources to

⁸ Food and Drug Administration, Department of Health and Human Services. Direct-to- Consumer Advertising Moratorium for Prescription Drugs Ended. 50 Federal Register 366-377.

⁹ Food and Drug Administration, Center for Drug Evaluation and Research, “Guidance for Industry Consumer-Directed Broadcast Advertisements, Questions and Answers,” August 1999, <http://www.fda.gov/cder/guidance/1804q&a.htm>.

¹⁰ Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donohue, Richard G. Frank, and Arnold M. Epstein; Promotion of Prescription Drugs to Consumers; New England Journal of Medicine, Volume 346, No. 7, February 14, 2002

¹¹ Ibid.

¹² Op. Cit. 1

gathering information so they can make informed decisions, but the time and money required limit the amount of information they gather. George Stigler shows that there is an optimal amount of search, which is a function of both the marginal cost and the marginal benefit of the search.¹³ Since DTC advertising lowers the marginal cost of the search for information, it leads to increased search and lower search costs. As a result, with DTC advertising consumers have more information about their health care choices and so are able to make better health care decisions. At the simplest level, this can mean that some consumers who might otherwise believe there is no reason for them to see a doctor will learn that their health can be improved if they do so.

Information about health care is a public good, and economic theory shows why public goods are often underproduced in the marketplace.¹⁴ Public goods, such as clean air, are difficult for private producers to provide because there is no way to limit their consumption to the individuals who have paid for them. To some extent, government and the popular press overcome the public good problem by providing health care information to consumers. However, there are many cases when the level of information provided by the government and the press is too low. For example, in the FTC's workshop, Sandra Raymond of the Lupus Foundation explained how advertising was critical in the 1980s to informing consumers about osteoporosis when adequate information was not being provided by other sources. Advertising provides additional information as well as a way for firms to overcome the public good issue and provide information to potential consumers. As such, DTC advertising helps make health care markets function better by providing health care information that in many cases would not otherwise be provided by public sources.

DIRECT TO CONSUMER ADVERTISING PROVIDES BENEFITS TO CONSUMERS

Advertising provides benefits to consumers by providing them with useful information (“...information is a valuable resource: knowledge is power¹⁵) and by reducing prices.

An important mechanism for disseminating information about product benefits in a market economy is advertising. The ability of sellers to advertise spurs competition among alternative products and alternative providers. The ability to advertise tends to reduce prices in markets for consumer goods and services as well as in markets for prescription drugs. Moreover, advertising tends to improve the product alternatives available to consumers and to produce better matching between individual consumers and the best product to serve their needs.¹⁶

Below, I expand on these benefits.

DTC Advertising Provides Consumers with Vast Amounts of Useful Information

¹³ George J. Stigler, *The Economics of Information*, *The Journal of Political Economy*, Volume LXIX, Number 3, June 1961

¹⁴ Pauline M. Ippolito and Alan D. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market* Bureau of Economics Staff Report, Federal Trade Commission, August 1989, page 18

¹⁵ *Ibid*, p 213

¹⁶ J. Howard Beales III, *FDA Regulation of Pharmaceutical Advertising: Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 *Seton Hall Law Review*, 1370. 1994,

Numerous studies have shown that DTC advertising provides useful, and perhaps even critical, information to consumers, helping them make better informed decisions, providing information that may not have been readily available, and even motivating them to visit doctors for previously untreated conditions. Thus, it lets them be active participants in managing their health care.

The FDA's Office of Medical Policy, Division of Drug Marketing, Advertising, and Communications of the Center for a Drug Evaluation and Research surveyed consumers in 1999 to learn more about DTC advertising. Results from the survey "Attitudes and Behaviors Associated with Direct-to-Consumer (DTC) Promotion of Prescription Drugs" show numerous aspects of how important DTC advertising is to consumers in managing their health care.¹⁷ Study results show that a large percentage of consumers see advertisements for both prescription and nonprescription drugs (responses to questions 4, 5, 8.) Advertisements cause about half of survey respondents to look for more information about the drug or their health (response to question 13.) They also cause significant number of patients to talk to doctors about conditions or illnesses they had not previously discussed (response to question 15.) About half of all respondents liked seeing advertisement for prescription drugs while only around 30 percent of the respondents did not like seeing the advertisement (response to question 34.) Over 85 percent of the respondents agreed that advertisements made them aware of new products. And perhaps most important, well over 40 percent of all respondents agreed that "Advertisement for prescription drugs help me make better decisions about my health" while less than 40 percent disagreed with the statement (response to question 41.) Finally, about 60 percent of the respondents agreed that "Advertisements for prescription drugs help me to have better discussions with my doctor about health" while only about 20 percent disagreed.

Prevention Magazine (with technical assistance from the FDA's Division of Drug Marketing, Advertising, and Communication) has also surveyed consumers for five years in a project which "measures and tracks consumer awareness of direct-to-consumer (DTC) advertising and assesses its overall effectiveness as a means of promoting both prescription medicines and public health."¹⁸ The findings of the survey also show that DTC has become an important component of the health care system and that advertising confers numerous benefits on American consumers, not all of which accrue from the increased uses of pharmaceuticals. According to the survey,

...DTC advertising motivated an estimated 61.1 million consumers to talk with their doctors about a health condition and possible treatments for it. For 60 percent of these consumers, these conversations include recommendations for non-drug therapies. Results also show that an estimated 24.8 million consumers were prompted by advertisements for prescription medicines to talk with their doctor about a health condition they had not previously discussed.¹⁹

¹⁷ accessed at www.fda.gov/cder/ddmac/dtcindex.htm

¹⁸ 5th Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines, 2001-2002, Prevention Magazine, p2.

¹⁹ Op. Cit. 13, p. 3

At a very high level, Prevention Magazine finds tremendous value in DTC advertising:

In short, DTC advertising is effective as a means of promoting prescription medicines and the public health for a very simple reason: it provides consumers with the information they need in order to take control of their own health and meet their growing need to participate in the management of their own care.²⁰

Years before the Prevention Magazine and the FDA surveys, the Bureau of Economics at the FTC performed two studies exploring the effect of advertising on information in the marketplace. The first studied the effects of advertising in the cereal market²¹ and the second studied the effects of advertising on fat and cholesterol consumption.²² Both studies found benefits from advertising. The Cereal study found “clear evidence that in the cereal market producer advertising and labeling added significant amounts of information to the market and reached groups that were not well reached by government and general information sources.”²³ And the conclusions of the study stated: “However, the study does make it clear that a policy that sharply limits advertising’s role in bringing evolving health information to consumers may come at a high information cost, whatever its other effects”²⁴

The Fat and Cholesterol study explored whether advertising claims “...have led to improvements in food choices, or as some fear, to confusion sufficient to undermine consumers' success in responding to the continuing public health advice on dietary choices.”²⁵ As the study notes,

Producer health claims have been controversial. While always subject to the normal legal rules for all claims -- claims must be truthful and not deceptive -- some believe that the increased use of health and nutrition claims in advertising and labeling during the late 1980s may have undermined consumers' ability to make more informed dietary decisions and may even have harmed consumers.²⁶

But the study found that this was not the case:

The results of this report do not support this premise, at least as it relates to fat, saturated fat, and cholesterol consumption. Between 1977 and 1985, available evidence indicates that consumption of these lipids fell, but between 1985 and 1990, when the regulatory environment governing diet-disease claims was relaxed to make it easier to make explicit claims,

²⁰ Op. Cit. 13, p. 5

²¹ Pauline M. Ippolito and Alan D. Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market, Bureau of Economics Staff Report, Federal Trade Commission, August 1989,

²² Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990, accessed at www.ftc.gov/be/fatexsum.htm

²³ Op. Cit. 21, page ix

²⁴ Op. Cit. 21, page 118

²⁵ Op. Cit. 22

²⁶ Op. Cit. 22

consumption of lipids fell faster. Individual food consumption data and food production data support the view that improvements in the consumption of fat, saturated fat, and cholesterol occurred faster in the post-1985 period and that the gains are widely shared across the population. Data on diet-disease knowledge is generally consistent with the behavioral evidence.

While we cannot conclusively determine how much of the added improvement is due to the information environment created by health claims *per se*, as opposed to continuing government and public health efforts to inform consumers, or to the general media coverage of these issues, nothing in the evidence suggests that these producer claims undermine consumer learning or efforts to improve diets. In fact, the available evidence examined here suggests that these diet-disease claims may have been beneficial to consumers overall by helping to foster an environment in which firms compete more directly on the nutritional features of their products and in which consumer learning and dietary change proceed more rapidly.²⁷

DTC Advertising Leads to Lower Prices

There have long been arguments over whether advertising raises prices or lowers them.

It has been argued that the persuasive aspects and the product differentiation effects of advertising tend to raise the prices of products to consumers. On the other hand, by providing consumers with information about products and alternatives in the market, allowing them to economize on search and to locate low-priced sellers more readily, advertising may tend to lower prices to consumers. It may also lower prices by allowing sellers or producers to economize on merchandising costs and to take advantage of economies of scale.²⁸

Despite the claims of critics of DTC advertising that this advertising increases prices of prescription drugs, empirical evidence suggests the opposite, namely that advertising leads to lower prices. An early study of price differentials of prescription eyeglasses in states that permitted advertising and those that didn't, found that "advertising restrictions in this market increase the prices paid by 25 percent to more than 100 per cent".²⁹ A summary of the effects of advertising on price states,

²⁷ Op. Cit. 22

²⁸ Lee Benham, The Effect of Advertising on the Price of Eyeglasses, The Journal of Law and Economics, October 1972, p. 337

²⁹ Ibid., p.344

The price reducing effects of advertising are not confined to the market for eyeglasses. Studies of legal services, advertising of prescription drugs by pharmacists, and retail gasoline price posting have all found that restrictions on the flow of information increase the price that consumers pay. Similarly, the introduction of toy advertising directed to children reduced prices.

Most of the available evidence concerns situations in which advertising has been entirely prohibited. Even where restrictions are less drastic, however, fewer restrictions on advertising are associated with lower prices...

The same competitive effects of advertising on prices also occur in prescription drug markets. When already-marketed products are approved for a new use, additional advertising by the entrant reduces the average price paid for all drugs used to treat that indication (relative to the prices of all drugs.) This effect occurs primarily because additional advertising by the entrant reduces the price of competitive products. Previous studies have also found that entry, assisted by pharmaceutical promotion, tends to reduce the price of competitive products.³⁰

FTC staff of the Bureau of Consumer Protection and the Bureau of Economics recently affirmed the view of the beneficial effects of advertising on price:

DTC prescription drug advertisements tend to focus on qualities of the drugs, not price. Economic research, however, suggests that consumers often infer that firms engaging in extensive nonprice advertising will also offer a better deal on price. Empirical studies of the prescription drug, eyeglass, and liquor industries find that advertising tends to reduce prices even when advertising of prices is prohibited. See Kyle Bagwell and Garey Ramey, *Advertising and Coordination*, 61 Review of Economic Studies 153-72 (1994).³¹

If we assume that DTC advertising has even the minimum effect on the price of pharmaceuticals that it does on prescription eyeglasses, then DTC advertising reduces consumer prices of pharmaceuticals by an enormous amount, even if the entire DTC advertising cost is passed on to consumers. For example, for the five classes of drugs explored by Rosenthal, et al., (antidepressants, antihistamines, antihyperlipidemics, nasal sprays, and proton pump inhibitors) DTC advertising costs were about \$554 million in 1999 while total sales were about \$23 billion.³² If lack of advertising increases prices by only 25 percent, then DTC advertising saved the consumers of these drugs one fourth of \$23 billion, or almost \$6 billion. Even netting out the DTC advertising costs would yield savings of about \$5.5 billion for just these five classes.

³⁰ Op. Cit. 15,

³¹ Comments of the Staff of the Bureau of Economics, Bureau of Consumer Protection, and Office of Policy Planning of the Federal Trade Commission, BEFORE THE OFFICE OF MANAGEMENT AND BUDGET; *In the Matter of* Agency Information Collection Activities; Submission for OMB Review; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer (DTC) Promotion Drugs; Survey, Docket No. 01N-0078, September 24, 2001

³² Op. Cit. 9, page 502

THE FEDERAL TRADE COMMISSION SHOULD CONTINUE ITS TRADITIONAL ROLE AS A STRONG ADVOCATE OF TRUTHFUL ADVERTISING

The FTC has long been a strong advocate of truthful advertising, recognizing the crucial role that it plays to the economy in general and to consumers. For example, in 1979, the Commission's statement of policy regarding comparative advertising noted:

Comparative advertising, when truthful and non-deceptive, is a source of important information to consumers and assists them in making rational purchase decisions. Comparative advertising encourages product improvement and innovation, and can lead to lower prices in the marketplace. For these reasons, the Commission will continue to scrutinize carefully restraints upon its use.³³

Advertising is so important to competition that the FTC regularly enforces the antitrust laws against efforts to suppress it. For example, the FTC objected to a group of automobile dealers' agreeing not to advertise in a newspaper which had offended them with an article on how to negotiate car prices.³⁴ In commenting on the case, then FTC Chairman Robert Pitofsky said:

By ensuring consumer access to advertising, this antitrust case is as important to consumers as the cases we bring to ensure that advertising is true and not deceptive. Advertising is a key source of price and other information and when competitors band together to restrict it, consumers lose.³⁵

Commission staff has also been strong advocates of truthful, direct to consumer advertising of drugs and health claims. In comments to the FDA, in 1996, they supported this position, writing, "We believe that truthful and non-deceptive DTC advertising can contribute to consumers' health information environment and consumer welfare."³⁶ They also provided further elaboration in these comments,

Truthful and non-misleading advertising can help consumers manage their own health care. Advertisements can, for example, provide timely information regarding medical advances, remind consumers about good health care

³³ **STATEMENT OF POLICY REGARDING COMPARATIVE ADVERTISING, FEDERAL TRADE COMMISSION, WASHINGTON, D. C. 20580, August 13, 1979**

³⁴ In re: Santa Clara Motor Car Dealers Ass'n, 120 F.T.C. 1032, December 13, 1995, Consent Order

³⁵ F.T.C. Press Release, Santa Clara County Auto Dealers Association Settles Charges Over Alleged Advertising Boycott, August 1, 1995

³⁶ In the Matter of Direct-to-Consumer Promotion; Public Hearing Docket No. 95N-0227, Comments of the Staff of the Bureau of Consumer Protection and the Bureau of Economics of the Federal Trade Commission, January 11, 1996 accessed at <http://www.ftc.gov/be/v960001.htm>

practices, and supply information needed by consumers to understand and evaluate their physician's recommendations.³⁷

The FTC reiterated these conclusions in comments to the FDA in 2002:

In short, the evidence currently available suggests that DTC advertising has had positive effects. DTC advertising appears to prompt consumers to seek out information about medications and medical conditions, some of which may not have been diagnosed previously. The information that consumers acquire may allow them to have enhanced conversations with their doctors about treatment options and may permit them to make better-informed health care decisions for themselves. The cost of providing the information appears to be low.³⁸

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MPA supports truthful DTC advertising. As these comments show, it provides information critical to letting Americans participate in and manage their health care. It also reduces the prices of prescription drugs. The FTC should continue to be a strong proponent of this advertising. The FTC should also consider conducting a study like those it conducted for cereals and for fats and cholesterol to determine the effects of DTC drug advertising.

³⁷ *Ibid.*

³⁸ Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission before the Department of Health and Human Services, Food and Drug Administration, in the Matter of Request for Comment on First Amendment Issues, Docket No. 02N-0209, September 13, 2002, page 31.