

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Request for Comment on  
Consumer-Directed Promotion  
[Docket No. 2003N-0344]

The Magazine Publishers of America appreciates this opportunity to respond to the FDA's request for comments dated August 12, 2003 and to supplement previous comments on prescription drug advertising submitted by MPA on September 16, 2002.

The Magazine Publishers of America ("MPA") is the premier trade association for the consumer magazine industry. MPA's more than 240 U.S. members publish approximately 1400 magazines, including some of the most widely distributed consumer publications in America, as well as local and specialized magazines.

These comments are written in response to Question 7, posed by the FDA in the aforementioned request for comments, and address trends in the development of patient information that affect how information is conveyed to consumers in Direct-to-Consumer (DTC) prescription drug advertising. To evaluate these trends, we spoke with pharmaceutical company representatives about why some companies are choosing to modify the brief summary in an effort to make it more effective and how they are achieving this objective.

The magazines published by MPA's members regularly include DTC prescription drug advertisements, which contain information relating to a medication's side effects, contraindications, safety, precautions, and effectiveness. This specific information, required by the Food and Drug Administration (FDA), is known as the brief summary.

The brief summary provides consumers with vital and useful information, which, studies have shown, can motivate consumers to see their physician about a particular health condition or medication, while providing them with enough information to have a well-informed discussion with their doctor. The brief summary in print advertisements is particularly useful to consumers because they are not only able to read the information, but review it as necessary. Research has shown that consumers believe the information in the brief summary is important. An AARP Public Policy Institute study revealed that 34 percent of those who report noticing the small print say they usually read it.<sup>1</sup>

Many advertisers typically fulfill the FDA's risk disclosure requirement by reprinting the risk-related section of a product's approved labeling (also called full prescribing information or the package insert) on the back page of the advertisement.<sup>2</sup> While this labeling includes essential consumer information, product labeling is generally written for health professionals and may be difficult for consumers to fully comprehend. Brief summaries may be enhanced by focusing more closely on the key pieces of information a consumer needs when deciding whether to speak to their physician about a health condition and advertised medication.

Data shows that well-communicated risk information often has positive effects on patients. For example, *Prevention* magazine's 1999 study shows that 53 percent of consumers who thought DTC advertising did an excellent job of providing information about serious product warnings talked with their doctors about a medicine as a direct result of seeing it advertised. In contrast, only 32 percent of consumers who thought the

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<sup>1</sup> "Are Consumers Well-Informed About Prescription Drugs? The Impact of Printed DTC Advertising." AARP. April 2000. Retrieved on November 14, 2003, from [http://research.aarp.org/health/2000\\_04\\_advertising\\_1.html](http://research.aarp.org/health/2000_04_advertising_1.html)

<sup>2</sup> Division of Drug Marketing, Advertising and Communications. "Frequently Asked Questions". Retrieved on November 14, 2003, from <http://www.fda.gov/cder/ddmac/FAQS.HTM>

ads did either a fair or poor job of providing this information spoke with their doctors about an advertised medicine.<sup>3</sup> In addition, *Prevention* magazine's survey shows that the presence of risk information in DTC advertisements may support enhanced compliance with prescribing instructions. For example, 22 percent of consumers who think DTC advertising does an excellent or good job of providing risk information say the advertising makes them more likely to take their medicines.<sup>4</sup> Well-communicated risk and benefits information can also encourage consumers to have their prescriptions refilled. Thirty-one percent of consumers who think DTC advertisements do an excellent job of providing information about serious product warnings say the ads actually make them more likely to have their prescriptions refilled.<sup>5</sup>

These findings have motivated an increasing number of pharmaceutical companies to improve and modify the brief summary to more effectively communicate understandable prescription drug information to consumers and consequently help improve health literacy, which is defined as the ability to read, understand, and effectively use basic medical instructions and information.

Low health literacy rates are emerging as a major problem in healthcare as an estimated 90 million adult Americans do not understand much of the patient education materials provided for them.<sup>6</sup> Studies show that people with low health literacy often require additional medical care that results in annual health care costs that are four times

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<sup>3</sup> Prevention: Consumer Reaction to DTC Advertising of Prescription Medicines - 5th Annual Survey - 2001-2002. Emmaus, PA: Rodale Press, Inc. 2002, p. 42.

<sup>4</sup> Prevention: Consumer Reaction to DTC Advertising of Prescription Medicines, p. 58.

<sup>5</sup> Prevention: Consumer Reaction to DTC Advertising of Prescription Medicines, p. 58.

<sup>6</sup> Partnership for Clear Health Communication. *What is Health Literacy?* (n.d.). Retrieved November 5, 2003, from [http://www.askme3.org/PFCHC/what\\_is\\_health.asp](http://www.askme3.org/PFCHC/what_is_health.asp)

higher than for those with higher literacy skills. In fact, low health literacy costs the health system as much as \$73 billion a year.<sup>7</sup>

Improving the readability of health communication, including the brief summary, is crucial to significantly increasing health literacy. Currently, most patient education is written at a tenth or twelfth grade reading level, but pharmaceutical companies are beginning to understand that health communications, including the brief summary, should be written at a sixth grade level. For example, replacing "placebo" with "sugar pill" is a relatively easy way companies can simplify language in brief summaries.

Pharmaceutical companies recognize the importance of patient education and some have re-evaluated and revised the brief summary in light of their dedication to improved health communication. A growing number of pharmaceutical companies are moving toward developing patient specific labeling (also called patient package inserts and patient information) for prescription medications.

Patient labeling fulfills the FDA's risk disclosure requirement by discussing all necessary risk information contained in product labeling, including contraindications, warnings, precautions, and side effects, but presents the information in consumer-friendly language understandable to patients. Some patient labeling use question and answer formats to convey information about prescription medications, while others use a combination of statements and questions to communicate risk and benefits.

Patient labeling has multiple uses and functions, encouraging increasingly more pharmaceutical companies to invest in its creation. Aside from being used for print advertisements, patient labeling may be distributed to physicians and medical centers to

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<sup>7</sup> Partnership for Clear Health Communication. *What is Health Literacy?* (n.d.). Retrieved November 5, 2003, from [http://www.askme3.org/PFCHC/what\\_is\\_health.asp](http://www.askme3.org/PFCHC/what_is_health.asp)

be given to patients, posted on Web sites, and used in brochures and other promotional materials.

Once pharmaceutical companies have decided to create patient labeling for a medication, they primarily use qualitative research to help determine the precise content of that patient labeling. For example, one company conducts in-depth one-on-one interviews with people who have not surpassed a high school education and who are currently suffering from the ailment the medication is designed to alleviate. A company representative works closely with that person, reviewing the patient labeling as many as twenty times to ensure each word is understandable and provides the information necessary for a consumer who either suspects they are suffering from the described ailment or is, in fact, suffering from the ailment. Physicians, pharmacists, and attorneys review the labeling as well to ensure it complies with all regulations and includes all required components.

Some companies are experimenting with other formats to improve their brief summaries, such as dramatically changing the layout and substantially increasing the font size and amount of white space. Other modifications include incorporating illustrations to help consumers understand how the medication works and how it should be taken. Modified designs frequently include bullet points listing side effects, warning signs, and instructions for use.

Improving the design and readability of brief summaries is one step in improving their effectiveness. Companies are also striving to improve the brief summary to more successfully engage consumers so that they go see their doctor, take their medication correctly, or have their prescription refilled. Pharmaceutical companies are finding that

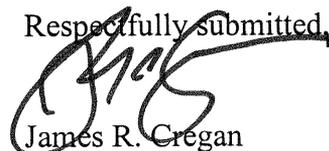
to achieve this objective, they must go beyond improving the readability and, in addition, address and answer the specific questions consumers may have about certain medications. Because consumers' questions can vary significantly depending on the medication and disease, patient labeling cannot be standardized by using the same approach and questions for every medication.

In addition, companies are finding that the order in which the information in the brief summary is presented is important. Presenting a large amount of risk information before conveying any of the benefits associated with a specific medication has been found to cause anxiety and discourage patients from taking action or pursuing more information. Companies are seeking to enable patients to consider both the benefits and risks of a drug when deciding how best to respond to an advertisement.

#### Conclusion

The brief summary is an important health communication tool, providing consumers with essential information related to a drug's risks and benefits. Pharmaceutical companies are working to improve patient education and more effectively communicate with consumers by enhancing the brief summary. With the ability to encourage patients to speak to their doctors, improve compliance with medication instructions, and increase the likelihood patients will have their prescriptions refilled, the brief summary can positively affect consumers and its improvement will surely increase its effectiveness.

Respectfully submitted,



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