

# **DTC Advertising Trends and PhRMA's "Guiding Principles"**

**Review Panel Observations and Recommendations**

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## Review Panel Observations and Recommendations

In April 2006, PhRMA's Office of Accountability initiated an independent, informal health professional review of direct-to-consumer (DTC) television advertisements for prescription medicines. The purpose of the review was to obtain transparent, unbiased feedback on pharmaceutical industry advertising with regard to PhRMA's voluntary *Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines*. A clear goal of the PhRMA principles is to enhance the educational value of prescription medicine advertisements. A complete list of the principles appears in Appendix 1.

To conduct their review, a four-person volunteer panel of health professionals (see below) observed direct-to-consumer television and print ads in the course of their everyday lives, from April 28<sup>th</sup> to September 29<sup>th</sup>, 2006. The panel communicated via e-mail and conference calls, during the five-

month period, and met as a group in September 2006. They subsequently shared the resulting observations with PhRMA at a January 16, 2007, meeting in Washington, DC. Because their review process was based on the panelists' experiences rather than scientific inquiry or surveys, panel members emphasized that their comments represented personal insights, and are purely anecdotal in nature. The group stated that their comments were only related to a subset of the principles. This is because some of the principles, such as numbers 4, 7, and 8, could not be assessed simply by observing an ad. Therefore, the group made it clear that it was not possible to reach any conclusions regarding drug manufacturers' compliance with the *DTCA Guiding Principles* document. The views of the panel members were theirs alone, and are not meant to reflect the views of others in their organizations or professions, or of the public at large.

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### INDEPENDENT REVIEW PANEL MEMBERS

**Lawrence "L.B." Brown, PharmD, PhD:** former speaker of the American Pharmacists Association House of Delegates and now an assistant professor of health science administration in the department of pharmaceutical sciences at the University of Tennessee.

**James G. Jones, MD:** former president of the organization that became the American Academy of Family Physicians. He is a professor and chairman *emeritus* in the department of family medicine at East Carolina University School of Medicine.

**Nancy J. Sharp, MSN, RN, FAAN:** founding executive director of the American College of Nurse Practitioners (ACNP) from 1993 to 1997. She has worked as a legislative and policy consultant for a number of nurse specialty organizations, including ACNP and the American Nephrology Nurses Association.

**Lucille C. Norville-Perez, MD:** 102<sup>nd</sup> president of the National Medical Association and now President and CEO of The Cave Institute as well as an assistant professor, Community and Family Practice, Howard University College of Medicine.

## **CURRENT DTC ADVERTISEMENTS: PANEL OBSERVATIONS**

The panel offered the following general impressions about the televised pharmaceutical ads they had seen with regard to the *DTC Guiding Principles*. Panel observations are organized by the principle(s) they address. Principle numbers appear in parentheses.

### **Educate consumers about the condition for which a medicine is prescribed (3); promote health and disease awareness (14).**

In the panel's experience, a few DTC campaigns ran ads that educated consumers about the relevant medical condition prior to launching product-specific ads. But most campaigns provided information about the condition. The panel noted that the most educationally-effective of the product-specific ads they saw promoted a prescription medication in the context of raising consumer awareness of a condition and its symptoms, and prompting contact with a health professional for further information and assessment. However, they reported that the balance of information in some DTC ads still emphasized the drug product rather than the condition.

*“I don’t believe that there is enough of the ad focused on a condition ... it’s peripheral to the drug ... in the vast majority of ads.”*

### **Foster patient/professional communication; educate health professionals about a product before a DTC advertising campaign begins (5, 6).**

The panel acknowledged that DTC advertising can prompt patient questions and dialogue about conditions and their treatment, and thus fosters communication. However, in the panel's perception, because of lack of access to information about medicines, many health professionals still feel unprepared to address patient issues about a new medicine when new DTC advertisements debut. The panel encouraged PhRMA to continue its efforts to reach out to health care providers to get additional feedback about how they prefer to learn about new medicines before they become available on the market.

*“Almost every day (in my practice) someone asks about ‘which kind of cholesterol do I have, doctor?’ ...I think that’s great proof that you can sell a product and educate the public about a health issue at the same time.”*

## **Present clear, balanced benefit/risk information that supports patient/professional dialogue (11).**

According to the panel, risk information was a common element of the ads they saw, but they preferred some approaches to others. For example, panelists commented that risk education in DTC ads could have greater impact when actors (rather than announcers) described risks directly to viewers. Panel members also emphasized the benefit of presenting risk information without distracting background visuals or activities. In the panel's view, an increasing number of DTC ads feature these practices, but they are not yet universal.

*“I would commend those companies that have done a good job of presenting the risk information without distraction.”*

## **Respect the seriousness of medical conditions (12).**

The best DTC ads use realistic presentations that respect viewer intelligence, panel members agreed. However, the light tone and minimally informative content of some DTC ads do not reflect the importance of the underlying health issues. The panelists expressed some concerns about ads that potentially glamorize a health condition (for example, by featuring celebrity patients in high-energy situations), or present unrealistically healthy patients who do not reflect the average consumer with the condition.

*“...The diversity can be better. Because it's not just having people of color in ads but accurately capturing their cultural difference in the ads... I'm beginning to see more of a flavor for that.”*

### **Target ad content and placement to respect age-group sensitivities (13).**

Panel members believe that, overall, DTC ads increasingly reflect this principle. Panelists noted a positive trend in terms of companies' sensitivity to timing and placement of ads, which was reflected in an apparent decline in early evening ads for adult-oriented products, such as erectile dysfunction medications. Panelists encouraged continued sensitivity to these issues, noting that a small number of such ads seemed to appear at inappropriate times toward the end of the review period.

*“We began this work in April. I noticed [that] all the ED ads went away in August during the ...6:30/7:30 time ... That’s a good thing.”*

### **Include information about help for the un- and underinsured (15).**

In the panel's experience, the vast majority of DTC ads did not include mention of PhRMA's Partnership for Prescription Assistance program or other assistance programs that provide low-cost or free medications to those in need. Members suggested that all ads should inform consumers of these resources.

## **PANEL RECOMMENDATIONS FOR FUTURE ACTION**

Currently, PhRMA is receiving input on DTC ads through the PhRMA.org Web site and from relevant professional organizations. The Office of Accountability then forwards any comments received relating to the principles to the relevant signatory companies. The panel proposed that PhRMA implement broader outreach methods to obtain consumer and professional opinions regarding DTC advertising. One suggestion was to create and leverage long-term partnerships with various health professional organizations. Another was to solicit comments about ad quality and provide feedback mechanisms, including the PhRMA Web site address, in DTC ads themselves.

Panel members also suggested approaches to obtaining a broader, more formal, and more definitive independent assessment of trends in DTC advertising in light of the *Guiding Principles*. For example, with the resources to obtain member mailing lists, panel members could formally solicit input from the large health professional organizations they represent. They also suggested that focusing attention on a cross-section of identified advertisements, selecting a few key principles for attention and specifying common criteria for assessment could give the review clear focus. Other suggestions included conducting surveys and focus groups of health professionals and consumers.

In addition, the panel suggested further clarification of the principles themselves. They encouraged PhRMA to explore additional opportunities to refine the principles' definitions or include additional "Q and A" resources that provide more specifics.

## APPENDIX I

### PhRMA's Voluntary Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines

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.
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.

