

2006

Office of Accountability Report II

Report of
Second Survey of
Signatory Companies

Open letter to Interested Parties:

We are pleased to present the second survey of signatory companies to the Guiding Principles on Direct-to-Consumer Advertising. This marks the end of the first year of the guidelines and we are pleased with the progress we are seeing in DTC advertising.

In 2005, the PhRMA Board of Directors unanimously adopted the Guiding Principles on Direct-to-Consumer Advertising. Our goals were simple and straightforward. We have long known that DTC communication—particularly television advertising—is a powerful tool for reaching and educating millions of people. As companies responsible for developing new and innovative medicines, we want patients and consumers to talk to their physicians about the medicines that may help them. We want them to have the information they need to improve their health. We also want them to better understand potential risks and side-effects. DTC advertising should and can be responsibly designed to achieve these goals and to encourage the appropriate use of medicines.

Direct-to-consumer advertising is already one of the most regulated forms of advertising. PhRMA's new Guidelines represent an additional layer of oversight—on top of the FDA advertising regulations—which our companies take very seriously. Under the FDA regulations, our advertising is already required to be accurate and not misleading; to only make claims supported by substantial evidence; to reflect fair balance between risks and benefits; and to be consistent with FDA approved labeling. The Guiding Principles go even further in the hopes that we can create messages that educate patients and consumers.

In addition to adopting the Principles themselves, companies also have taken the extra step to establish their own internal processes to educate employees and agencies they work with about their importance. Signatory companies are reporting unanimously that this internal education process is now well established.

The third and final layer of oversight was created with the Office of Accountability, which is designed to receive comments about DTC advertising and to forward them to the appropriate companies. This year, we had several comments, both positive and negative, which you will read about further in this report. We consider all comments productive and are pleased that consumers and healthcare professionals are beginning to learn about this important mechanism.

With these Principles, the industry is recognizing that it is our responsibility to make sure that direct-to-consumer advertising is educational, appropriate and ultimately a benefit to patients. The first year has marked a tremendous growth period for us and the progress, we believe, is good. We look forward to a bright and informative future for patients and consumers.

Sincerely,

Billy Tauzin

INTRODUCTION

On July 19, 2005, PhRMA's Board of Directors unanimously approved Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines. These principles express the voluntary commitment of PhRMA members to enhance the educational and informative nature of their DTC communications in the interest of better serving the public health. These Guiding Principles help ensure that DTC advertising remains an important and powerful tool to educate patients while at the same time addressing many of the concerns publicly expressed about DTC advertising over the past few years.

Pursuant to the Principles, PhRMA established an Office of Accountability to receive comments about signatory companies' compliance with the Guiding Principles and to forward those comments to the appropriate member company for further consideration. Additionally, the Guiding Principles state that the Office of Accountability will issue periodic reports to the public regarding the nature of the comments and the signatory companies' responses, and will provide a copy of each report to the FDA. The first such report was issued by the Office of Accountability in September 2006. This is the second report covering the time period of July 1, 2006 – December 31, 2006.

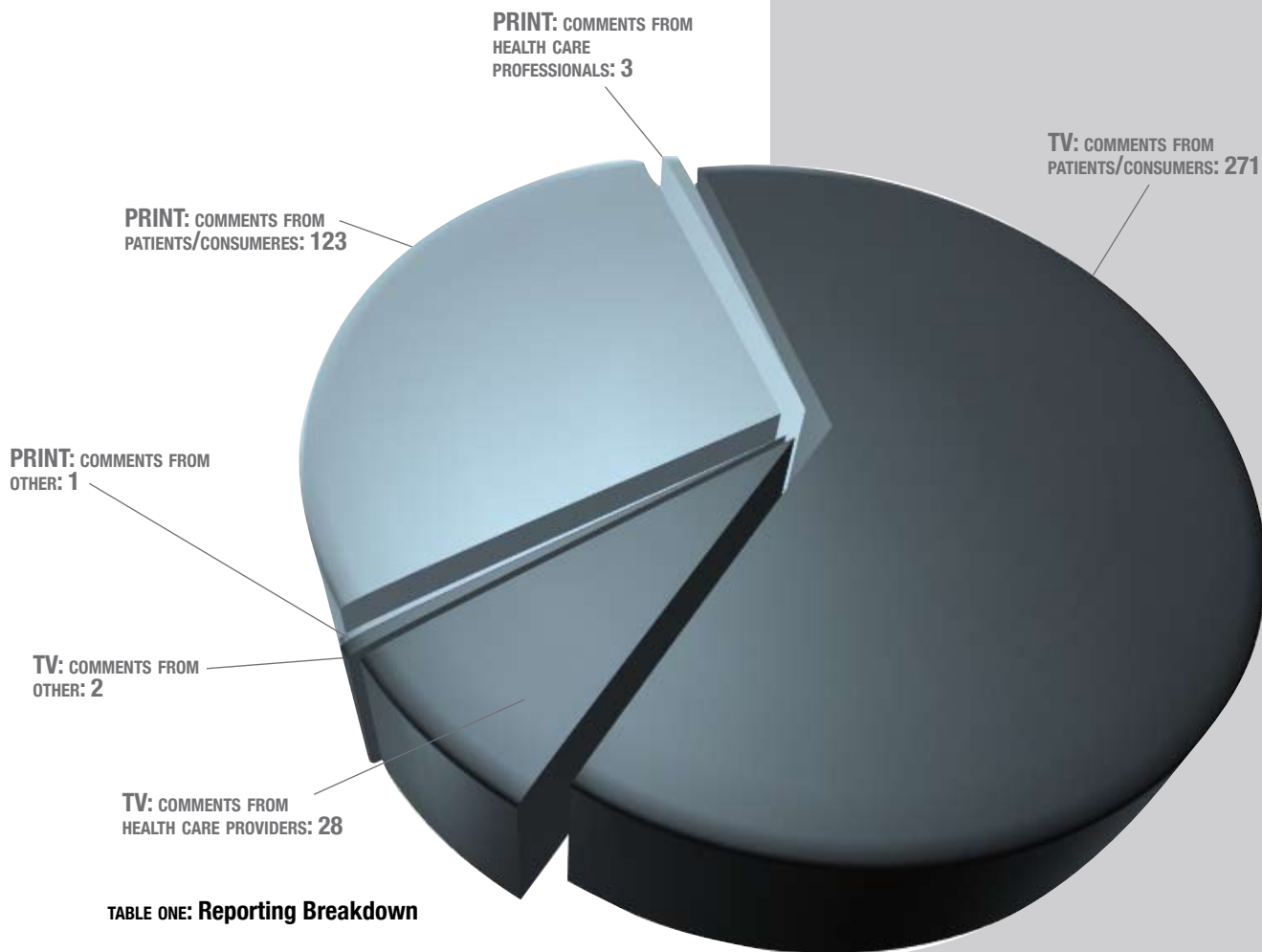
METHODOLOGY

PhRMA's Office of Accountability conducted a survey of all signatory companies in January 2007 asking them for the number and nature of comments they received (both through the Office as well as independently) between July 1, 2006, and December 31, 2006. Unless otherwise indicated, all information provided in this report is based solely on signatory companies' survey responses.

SURVEY RESULTS

Signatory companies reported receiving a total of 458 comments during the second six months of 2006. Of those, 330 comments (72%) related to television advertisements, and 128 (28%) related to print advertisements.

The majority of comments (271) received by signatory companies were submitted by patients or consumers. Twenty-eight comments were submitted by health care professionals, and two came from other sources.



SUMMARY OF COMMENTS RELATING TO THE GUIDING PRINCIPLES

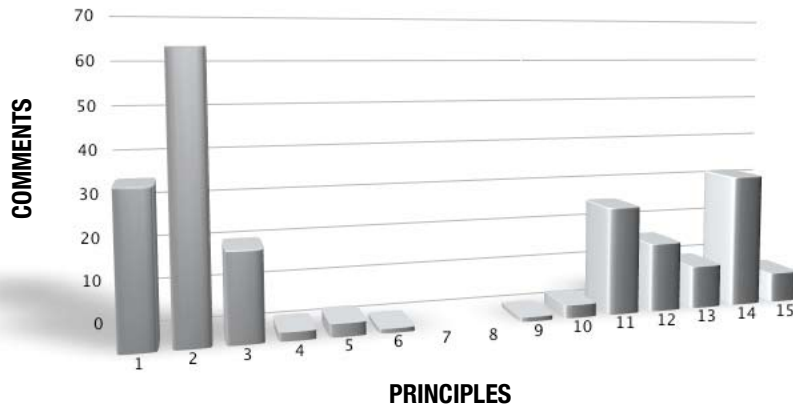
The Office of Accountability is pleased to report the survey results from the second six month period that PhRMA's Guidelines on DTC advertising have been in place. All participating companies have developed and maintain internal procedures to implement the PhRMA Guidelines on DTC advertising and have trained or made aware their media and advertising partners about their need to adhere to the Guidelines.

In the six-month period from July 1 to December 31, 2006, PhRMA companies received a total of 458 comments on adherence to the Guiding Principles. The vast majority of comments came from patients/consumers; less than 10% came from healthcare providers.

Most comments received concerned the public health benefits of DTC advertising such as disease and product awareness (Principle 1) and the advertisements' compliance with FDA regulations (Principle 2). The comments on Principle 1 were both positive – with many patients having favorable reactions to the educational component of an ad – and negative – primarily with regard to specific actors used in the advertisement. The comments on Principle 2 dealt primarily with the need for clarification around the specific details of an advertisement. All companies receiving comments responded to requests and questions, and one company revised an advertisement pursuant to the comment received.

There were 21 comments on the educational value of DTC

TABLE TWO: Comments Relating to Principles



advertising about the product and condition for which it may be prescribed: Principle 3. Many consumers were appreciative of the information provided while others stated confusion about the details of the advertisement and asked for further clarification. All companies responded to comments they received.

Very few comments were received on principles 4, 5, 6, 7, 8, 9, and 10.

Principle 11, which addresses the need for a balanced representation of risk/benefits, received 25 comments. Most related to confusion about risk information presented, difficulty reading the font in an ad, and/or the need for clarification of purpose of the medicine or therapy in advertisement.

Sixteen people commented on Principle 12, which states that advertising should respect the seriousness of the health

conditions and medicines being advertised. Most comments expressed distaste for the choice of creative concept in the advertisement.

Ten people commented about the placements of advertisements to avoid audiences that are not age appropriate for the messages being delivered (Principle 13). Some comments applauded companies for improving the timing of their advertisements while other noted that some ads were being aired during times that exposed minors to inappropriate content. Companies receiving these complaints responded that, per the principle, they target their ad placement for programming with at least 90% adult viewers.

Principles 14 and 15, which encourage companies to promote health and disease awareness and programs that help the uninsured/underinsured, received 43 comments. The comments were overwhelmingly positive—thanking the companies for offering product assistance and asking for further information about specific diseases or assistance programs. A few negative comments expressed concern about companies perceived insensitivity to those suffering from a specific disease.

GUIDING PRINCIPLES

1. These Principles are premised on the recognition that DTC advertising of prescription medicines can benefit the public health by increasing awareness about diseases, educating patients about treatment options, motivating patients to contact their physicians and engage in a dialogue about health concerns, increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated, and encouraging compliance with prescription drug treatment regimens.
2. In accordance with FDA regulations, all DTC information should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labeling.
3. DTC television and print advertising which is designed to market a prescription drug should also be designed to responsibly educate the consumer about that medicine and, where appropriate, the condition for which it may be prescribed.
4. DTC television and print advertising of prescription drugs should clearly indicate that the medicine is a prescription drug to distinguish such advertising from other advertising for non-prescription products.
5. DTC television and print advertising should foster responsible communications between patients and health care professionals to help patients achieve better health and a more complete appreciation of both the health benefits and the known risks associated with the medicine being advertised.

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