



2017

Report of the PhRMA Member Signatory
Companies to the PhRMA Guiding Principles on
Direct to Consumer Advertisements (DTC) about
Prescription Medicines

Volume XIII

Introduction

The Pharmaceutical Research and Manufacturers of America's (PhRMA) *Guiding Principles on Direct-to-Consumer (DTC) Advertisements about Prescription Medicines* ("PhRMA Guiding Principles") affirm the industry's commitment to providing accurate, accessible and useful information on innovative medicines to patients and consumers. A list of the principles in effect for 2017 can be found as Appendix A to this report.

Pursuant to the PhRMA Guiding Principles, PhRMA welcomes public comments about signatory companies' compliance with the PhRMA Guiding Principles and forwards those comments, if any, to the appropriate member company for further consideration. In addition, PhRMA annually surveys PhRMA member companies that are signatories to the PhRMA Guiding Principles about comments that the companies received, and it prepares a summary report of the companies' responses. **This is the 13th volume published and it covers the period from January 1, 2017 to December 31, 2017.**

A list of companies that are signatories to the current version of the PhRMA Guiding Principles can be found at <https://www.phrma.org/media/certification-submission>.

Methodology

To prepare this report, PhRMA conducted a survey of signatory companies that are current PhRMA members requesting information regarding the number and nature of comments that signatory companies had received between January 1, 2017 and December 31, 2017. Unless otherwise indicated, all information provided in this report is based solely on survey responses from 15 signatory companies.

Comments or questions about this report can be directed to PhRMA at dtc@phrma.org.

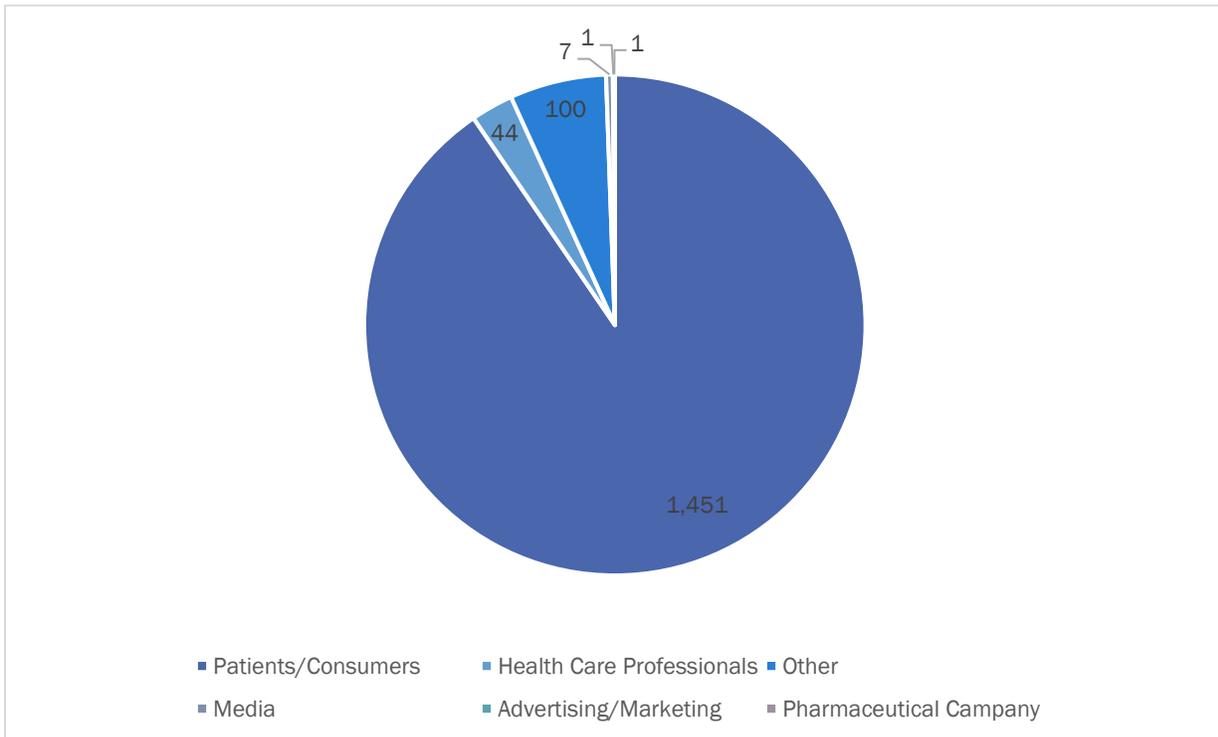
Survey Results

Fifteen of the survey respondent companies stated that they had developed and continued to maintain internal policies and procedures to foster compliance with the then-current version of the PhRMA Guiding Principles. Those 15 companies also responded that they trained or informed their media and advertising partners about their imperative to adhere to the Principles.

Survey respondents reported that they received a total of 1,604 comments relating to DTC advertisements that were associated with television, print or online advertising during the time period covered by the survey. Of those comments, 1,312 related to television advertising, 59 related to print, and 233 related to online or other advertising.

The majority of comments received by signatory companies were submitted by patients and consumers (1,451 comments or 90 percent). Other comments were submitted by health care professionals (44 comments or 3 percent), media (7 comments or less than 1 percent), advertising or marketing professionals (1 comment or less than 1 percent), pharmaceutical company (1 comment or less than 1 percent) and other uncategorized commenters (100 comments or 6 percent).

Who Submitted Comments?



Of the 1,604 comments received regarding DTC advertisements, not all were related to a specific PhRMA Guiding Principle in the determination of the survey respondents. Each survey respondent makes the determination as to which, if any, principle a comment is related. Further, commenters are not always aware that their comment is or is not related to a specific principle.

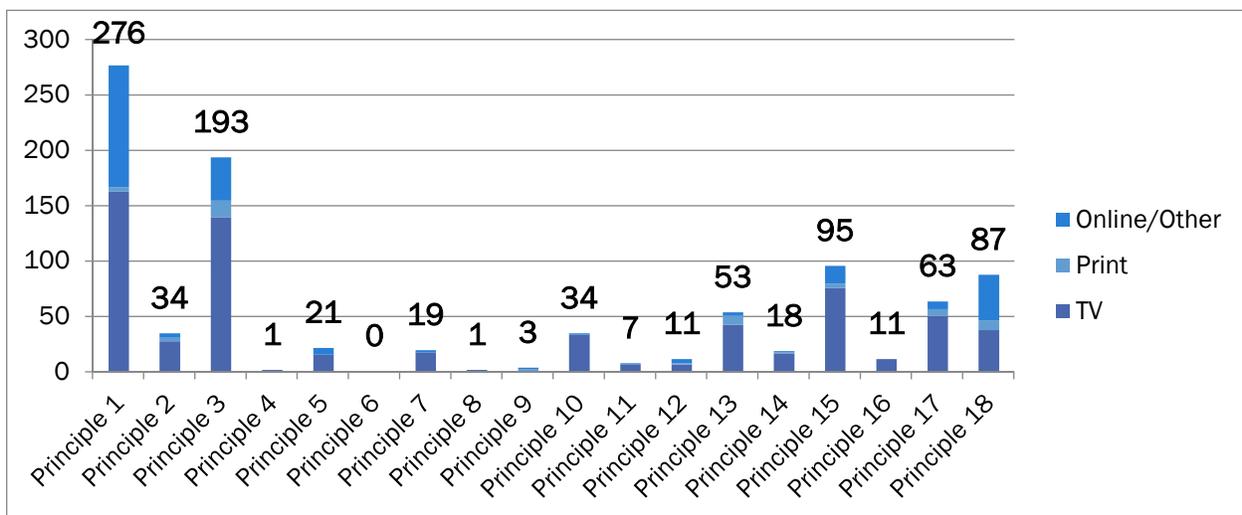
Survey respondents reported that approximately 42 percent (677) of the 1,604 comments on DTC advertisements fell within the scope of the principles but were not associated with a specific principle or did not relate to the PhRMA Guiding Principles. These comments were both negative and positive in nature and included feedback not pertaining to drugs or diseases, questions about specific products, comments regarding the cost of advertising in relation to the cost of medicines, both negative and positive comments about the creative

approach in television and print advertising, feedback on quality of advertisements, complaints about the placement in programming and frequency of television advertisements and general displeasure about advertising. Signatory companies reported that they responded to all substantive questions or comments.

Summary of Comments that Related to the PhRMA Guiding Principles

Characterized below are comments that were determined by the survey respondents to fall under specific PhRMA Guiding Principles in effect in 2017.

Number of Comments by Principle and Advertising Type



Comments by Principle

Companies received 276 comments relating to **Principle 1**, which refers to the public health benefits of DTC advertising. Comments included compliments around benefits of DTC advertising to public health, improvements to their lives, the understanding of the disease state, and suggestions for improvement on product packaging or website.

Companies received 34 comments related to **Principle 2**, which calls for compliance with FDA regulations and labeling standards. Comments focused on the balance between the risks and benefits of a medicine. One commenter questioned the accuracy of scientific information in the advertisement.

Companies received 193 comments related to **Principle 3**, which addresses the educational value of DTC advertising and the importance of obtaining appropriate feedback prior to airing/publication. Positive comments centered on helpful information in

the ad and product website and praise for a nurse ambassador program. Some commenters reported positive health benefits from the medicine. Other comments related to the reasonable education of consumers about medicines and diseases and questions about how a drug works or how to use it.

One comment was received related to **Principle 4**, which states that 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.

Companies received 21 comments related to **Principle 5**, which addresses the importance of communication between patients and health care professionals. Comments related to the responsible communication between health care providers and patients. Other commenters were seeking more information about the product in general and its side effects.

Companies received 19 comments related to **Principle 7**, which addresses when 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.

One comment was received that related to **Principle 8**, which calls for companies to submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.

Companies received three comments relating to **Principle 9**, which calls for all DTC print advertisements for prescription medicines should include FDA's toll-free MedWatch telephone number and website for reporting potential adverse events.

Companies received 34 comments related to **Principle 10**, which states advertising should acknowledge when companies feature actors in the roles of health care professional, and likewise, if actual health care professionals appear in advertising, the advertisement should include an acknowledgement if the health care professional is compensated for the appearance. General comments focused on compensation for actors and patients appearing in advertisements and the importance of acknowledging actors in advertisements.

Companies received seven comments related to **Principle 11**, which states, where a DTC television or print advertisement features a celebrity endorser, the endorsements should accurately reflect the opinions, findings, beliefs or experience of the endorser. Companies should maintain verification of the basis of any actual or implied endorsements made by the celebrity endorser in the DTC advertisement, including whether the endorser is or has been a user of the product if applicable.

Companies received 11 comments related to **Principle 12**, which states that 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. Comments focused on using alternative treatments and availability of other treatment options.

Companies received 53 comments related to **Principle 13**, which states that DTC television advertising that identifies a product by name should clearly state the health condition for which a medicine is approved and major risks associated with the medicine.

Companies received 18 comments relating to **Principle 14**, which addresses the need for fair balance between benefits and risks associated with an advertised prescription medicine. Comments included general concerns about the seriousness of the side effects mentioned in the ad, requests for more information about the side effects and questions received related to the balanced presentation of both benefits and risks of the product in the ad.

Companies received 95 comments relating to **Principle 15**, which states that all DTC advertising should respect the seriousness of the health conditions and medicines being advertised. Some comments were critical in nature of how the advertisements were not respecting the seriousness of the disease or condition. Other negative comments focused on not using sick patients in advertisements and the impact of the disease being misrepresented. Positive comments centered on how patients were portrayed in the advertisement.

Companies received 11 comments relating to **Principle 16**, which states that DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved. One comment found an advertisement to be using inappropriate hand gestures.

Companies received 63 comments relating to **Principle 17**, which encourages companies to promote health and disease awareness as part of their DTC advertising. Comments were generally focused on the promotion of disease and health awareness. Compliments were received around disease awareness campaigns.

Companies received 87 comments related to **Principle 18**, which addresses the goal of including information in DTC advertising about help for uninsured or underinsured. Comments focused on the affordability of medicines and access, and support from the company in lowering the cost. Other comments centered on copay cards and coupons, patient assistance programs, lack of insurance coverage, difficulty with obtaining prior authorization, confusion about messaging related to pricing, and free trial offers.

Appendix A

PhRMA Guiding Principles: Direct-to-Consumer Advertisements About Prescription Medicines

Principle 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.

Principle 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. Accordingly, companies should continue to base promotional claims on FDA approved labeling and not promote medicines for off-label uses, including in DTC advertisements.

Principle 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. During the development of new DTC television advertising campaigns, companies should seek and consider feedback from appropriate audiences, such as health care professionals and patients, to gauge the educational impact for patients and consumers.

Principle 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.

Principle 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.

Principle 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 and to alert them to the upcoming advertising campaign 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 are encouraged to consider individually setting specific periods of time, with or without exceptions, to educate health care professionals before launching a branded DTC television or print advertising campaign. Companies should continue to educate health care professionals as additional valid information about a new medicine is obtained from all reliable sources.

Principle 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.

Principle 8:

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

Principle 9:

DTC print advertisements for prescription medicines should include FDA's toll-free MedWatch telephone number and website for reporting potential adverse events. DTC television advertisements for prescription medicines should direct patients to a print advertisement containing FDA's toll-free MedWatch telephone number and website, and/or should provide the company's toll-free telephone number.

Principle 10:

Companies that choose to feature actors in the roles of health care professionals in a DTC television or print advertisement that identifies a particular product should acknowledge in the advertisement that actors are being used. Likewise, if actual health care professionals appear in such advertisements, the advertisement should include an acknowledgement if the health care professional is compensated for the appearance.

Principle 11:

Where a DTC television or print advertisement features a celebrity endorser, the endorsements should accurately reflect the opinions, findings, beliefs or experience of the endorser. Companies should maintain verification of the basis of any actual or implied endorsements made by the celebrity endorser in the DTC advertisement, including whether the endorser is or has been a user of the product if applicable.

Principle 12:

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.

Principle 13:

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.

Principle 14:

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, including the substance of relevant boxed warnings, should be presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content. In addition, DTC television advertisements should support responsible patient education by directing patients to health care professionals as well as to print advertisements and/or websites where additional benefit and risk information is available.

Principle 15:

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

Principle 16:

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. In particular, DTC television and print advertisements containing content that may be inappropriate for children should be placed in programs or publications that are reasonably expected to draw an audience of approximately 90 percent adults (18 years or older).

Principle 17:

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

Principle 18:

Companies should include information in all DTC advertising, where appropriate, about help for the uninsured and underinsured.