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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852\

RE: FDA Request for Comments on Consumer-Directed Promotion of Regulated Medical Products; 70 Fed. Reg. 54054 (September 13, 2005), Docket No. 2005N-0354

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is pleased to submit these comments on consumer-directed promotion of regulated medical products in response to the Federal Register notice published by the Food and Drug Administration (“FDA”) on September 13, 2005. PhRMA is a voluntary, non-profit trade association that represents the country’s leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer and more productive lives. Investing almost \$40 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

PhRMA companies devote substantial resources not only to discovering and developing new medicines, but also to informing and educating healthcare professionals and patients about the availability, proper usage, and risks associated with those medicines. Accordingly, PhRMA and its member companies have a significant interest in FDA regulation of direct-to-consumer (“DTC”) promotion of pharmaceuticals. PhRMA provided oral testimony during the Agency’s public hearing on DTC promotion held on November 1-2, 2005. The following written comments are intended to supplement that testimony.¹

I. Introduction

PhRMA is pleased that many of the presenters at the public hearing confirmed the tremendous value of DTC advertisements in conveying useful health information to patients. Research demonstrates that DTC advertising helps educate patients about medical conditions and treatment options, encourages dialogue between patients and physicians, prompts large numbers

¹ Because PhRMA represents research-based pharmaceutical and biotechnology companies, these comments do not address DTC promotion of medical devices.

of Americans to discuss illnesses with their physicians for the first time, and promotes improved compliance with physician-prescribed treatments.

Because of the special nature of prescription drug products, DTC advertising of drugs is subject to stringent regulatory requirements and oversight by FDA. This strict oversight is appropriate for products as powerful and important as prescription drugs and has been effective at ensuring that the vast majority of DTC advertisements present truthful, accurate, well-balanced and useful healthcare information to patients.

PhRMA believes that FDA's existing regulatory policies for DTC advertising are rigorous and effective and do not require major revisions. At the same time, PhRMA acknowledges that key stakeholders, including physicians, patients and policymakers, have expressed concerns about the content of DTC advertising and its effects on consumers, physicians and the healthcare system in general. Although there is little robust evidence to support the contention that DTC advertising leads to inappropriate prescribing or drug use,² PhRMA takes the stakeholders' concerns very seriously. In order to address these concerns, on July 29, 2005, the PhRMA Board of Directors unanimously approved PhRMA's *Guiding Principles on Direct-to-Consumer Advertising About Prescription Medicines*. The PhRMA Guiding Principles reiterate our members' commitment to the existing high regulatory requirements for DTC advertising but also express a commitment to go beyond those requirements in many respects, such as pre-submitting broadcast advertisements with FDA. PhRMA believes that the *Guiding Principles* will effectively address many of the issues raised by concerned stakeholders and in FDA's Federal Register notice.

Although the existing regulatory structure generally works well, particularly when paired with responsible industry self-regulation, PhRMA supports limited revisions to FDA's regulatory policies, particularly to maximize the communication and comprehension of benefit and risk information. For example, PhRMA strongly supports FDA's efforts to improve the usefulness and impact of the brief summary in DTC print advertisements (as described in Section IV.G).

These revisions, however, should be carefully targeted and should take into account three overarching principles. First, any FDA approach to regulating DTC advertising should reflect the paramount importance of the physician in deciding whether a particular medicine is appropriate for a particular patient. Second, new approaches for communicating benefit and risk information should be data-driven, relying upon adequate consumer research to demonstrate increased consumer comprehension (as described in Section V). Finally, FDA must ensure that any revised policies are consistent with the First Amendment and do not impose unnecessary restrictions on truthful and accurate DTC advertising (as described in Section VI).

² See Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission on Request for Comments on Consumer-Directed Promotion, Docket No. 2003N-0344 (Dec. 1, 2003).

PhRMA firmly believes that when patients have access to accurate and understandable information about medical conditions and treatment options, they can partner more effectively with their healthcare providers to obtain the most appropriate treatment, considering their individual circumstances.

II. The Value of DTC Communications

DTC advertising plays an essential role in meeting the needs of an increasingly sophisticated, information-seeking health care consumer. An important benefit of DTC advertising is that it fosters an informed conversation about health, disease and treatments between patients and their healthcare practitioners. DTC advertising also serves a valuable role in educating patients about the limitations and risks associated with certain therapies. And because DTC advertising has the potential to reach millions of Americans about healthcare treatments, DTC communications can be of tremendous value in conveying useful health information to patients.

The benefits of DTC communications to the public health are manifold and have been documented in numerous studies. These benefits include:

- Providing patients with important and useful information on available treatments and their benefits and risks;
- Encouraging productive communications between patients and their doctors;
- Motivating people to seek additional health information from other sources;
- Motivating people to visit a physician; and
- Enhancing patient compliance with prescribed treatment regimens.

Moreover, there is little or no evidence to support claims that DTC advertising leads to inappropriate prescribing or drug use or inappropriate pressure to prescribe an advertised drug product.³ In fact, much of DTC advertising is for categories of medicine that are underused. In light of the documented pattern of under-treatment of serious conditions – such as asthma, depression, high cholesterol, diabetes and many others – outreach via DTC advertising can help patients get much needed treatment.

A. DTC Communications Provide Patients With Important and Useful Information About Available Treatment Options

Today, the vast majority of adults believe they need to take a more active role in managing their healthcare. Consumers value DTC as a resource for current information about treatment options. In FDA's 2002 survey, three-quarters of consumers reported that DTC ads increased their awareness of new treatment options, and 72% said that ads "educate people about the risks and benefits of prescription medicines."

³ E. A. McGlynn et al., "The Quality of Health Care Delivered to Adults in the United States," *New England Journal of Medicine* 348, no. 26 (23 June 2003): 2635–2645.

Consumers are not alone in perceiving the health benefits of DTC. Physicians also recognize a positive effect. The Harvard/Harris study, for example, found that 72% of physicians somewhat or strongly agree that DTC ads help educate and inform patients about treatments available to them.⁴

B. DTC Communications Encourage Productive Communications Between Patients and Their Physicians

Survey data also indicate that discussions between patients and their physicians triggered by a DTC advertisement are thoughtful and productive. In the FDA survey, patients almost universally (93%) reported that their doctor “welcomed their questions.” Similarly, 41% of physicians participating in FDA’s survey reported that DTC advertising benefited their interaction with patients. Reported benefits included improved discussions with patients, greater patient awareness of treatments, and more informed/educated patients.

Most physicians (73%) also agreed that their patients asked thoughtful questions because of a DTC advertisement. According to surveyed physicians, DTC advertising also causes patients: (a) to be more concerned about their health and involved in their healthcare, (b) to become aware of problems earlier, and (c) to seek treatment for potentially serious conditions.⁵ The Harvard/Harris National physician survey produced similar results: 73% of physicians agree that DTC advertising helps educate patients, and 67% agree that DTC advertising helps physicians have better discussions with patients.⁶

As FDA itself has acknowledged, research indicates that greater patient involvement in healthcare may lead to better health outcomes.⁷ By prompting more productive doctor/patient dialogue and furthering consumers’ interest in their own healthcare, DTC advertising enables consumers to more effectively partner with their healthcare providers to determine appropriate treatments.

⁴ Joel S. Weissman, Ph.D., et al., *Consumer and Physician Reports on the Health Effects of DCTA*, (Harvard/Harris Study (2003)), <http://www.fda.gov/cder/ddmac/PIweissman/index.htm>. Similar results were obtained by the FDA in their survey of physicians. In this study, 72% of physicians agreed that DTC increases awareness of treatments in general.

⁵ K. Akin et al., *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results*, Final Report (Nov. 19, 2004).

⁶ J. S. Weissman, et al., *Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising*, Health Affairs, W4-219-W4-233 (April 28, 2004).

⁷ K. Akin et al., *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results*, Final Report (Nov. 19, 2004).

C. DTC Communications Motivate People to Seek Additional Health Information

While DTC advertisements alone cannot be expected to provide all the information necessary to inform a decision about a particular prescription drug, the ads motivate consumers to consult other available information sources, including their physicians, to learn more about the benefits and risks of treatment options.⁸ In the 2002 FDA patient survey, 43 percent of respondents reported that a DTC ad caused them to look for more information about the medicine or their health. Among respondents who said a DTC ad motivated them to search for additional information, the most commonly mentioned sources were healthcare providers, reference books, and friends, relatives, or neighbors. The Internet is also becoming an increasingly important source of health information. The number of people using the Internet to find additional information increased from 18 percent in 1999 to 38 percent in 2002.⁹

D. DTC Communications Motivate Patients to Visit A Physician, Often Resulting In New Diagnoses

FDA's 2002 patient survey confirms that consumers exposed to DTC advertising seek additional information either about advertised drugs or their health, and that the vast majority (89%) seek this follow-up information from their doctors. Almost a third of physicians participating in FDA's survey reported that DTC advertising encourages hard-to-reach patients to visit their doctors.¹⁰ Similarly, a multi-year tracking study conducted by *Prevention* and *Men's Health* magazines found that in each of the years 1997 through 2002, approximately one-third of survey respondents – a total of 64.7 million consumers – had talked with a physician as a result of seeing a DTC ad.¹¹ A third survey, the Harvard/Harris National patient survey, found that 35% of consumers had been prompted by a DTC ad to talk to a doctor about an advertised drug or other health issue or concern.¹² Studies suggest that product specific advertisements may be more effective at motivating patients to consult a physician than general “disease-awareness”

⁸ In annual studies conducted by Prevention Magazine, 85% of patients surveyed agreed that DTC advertisements encourage people to find out more about the advertised drug, while 83% agreed the advertisements encourage people to find out more about the condition the drug treats. Edwin Slaughter, *Consumer Reaction to DTC Advertising of Prescription Medicines 1997 to 2002*, (Prevention Annual Survey (2002)), available at <http://www.fda.gov/cder/ddmac/P1Slaughter/index.htm>

⁹ FDA patient surveys, 1999 and 2002.

¹⁰ K. Akin *et al.*, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results*, Final Report (Nov. 19, 2004).

¹¹ E. Slaughter, *Consumer Reaction to DTC Advertising of Prescription Medicines 1997 to 2002*, A Six-Year Tracking Study from Prevention and Men's Health Magazines, presentation available at <http://www.fda.gov/cder/ddmac/P1Slaughter/index.htm>

¹² J. S. Weissman, *et al.*, *Consumers' Report on the Health Effects of Direct-To-Consumer Advertising*, Health Affairs, W3-82-W3-95 (Feb. 26, 2003).

ads because product specific ads offer a potential solution whereas disease-awareness ads do not.¹³ Based on these surveys and research, it is clear that DTC promotion motivates consumers to discuss health concerns with their healthcare providers.

Multiple surveys show that exposure to DTC advertisements prompts consumers to ask physicians about problems that had not been discussed previously. The *Prevention* and *Men's Health* tracking study found that 29.4 million Americans spoke with their doctor about a medical condition for the first time as a result of seeing a DTC advertisement between 1997 and 2002.¹⁴ Similarly, nearly one in five patients participating in FDA's survey reported speaking to a physician about a condition for the first time because of a DTC ad.¹⁵ Data from the Harvard/Harris National patient survey confirms these findings and also shows that these DTC-prompted discussions lead to important new diagnoses. In that survey, almost 22% of consumers who initiated a discussion with their doctor as a result of a DTC ad discussed a new health concern, and almost 25% (representing approximately 16 million consumers) were diagnosed with a new condition during the doctor visit. Notably, approximately 43% of the new diagnoses were "high priority" conditions, such as high cholesterol, high blood pressure, diabetes and depression, which often are under-diagnosed or under-treated.¹⁶

These new diagnoses allow earlier intervention and treatment, helping patients avoid more costly treatments, such as surgery and/or hospitalization, and unnecessary suffering.

E. DTC Communications Enhance Patient Compliance

Another benefit of DTC advertising is its positive impact on patient compliance with physician-prescribed treatment regimens. Physicians participating in the FDA survey reported that DTC advertising enhanced patient compliance: one third thought that DTC advertising increased the likelihood of proper medication usage and close to one third believed that it helps patients adhere to their treatment regimen.¹⁷ Similarly, 46% of physicians surveyed in the

¹³ Testimony of Patrick Kelly, President, US Pharmaceuticals, Pfizer, before the Food and Drug Administration, Public Hearing on Direct-to-Consumer Promotion of Medical Products, November 1, 2005.

¹⁴ E. Slaughter, *Consumer Reaction to DTC Advertising of Prescription Medicines 1997 to 2002*, A Six-Year Tracking Study from *Prevention* and *Men's Health* Magazines, presentation available at <http://www.fda.gov/cder/ddmac/P1Slaughter/index.htm>

¹⁵ K. Akin *et al.*, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results*, Final Report (Nov. 19, 2004).

¹⁶ J. S. Weissman, *et al.*, *Consumers' Report on the Health Effects of Direct-To-Consumer Advertising*, Health Affairs, W3-82-W3-95 (Feb. 26, 2003).

¹⁷ K. Akin *et al.*, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results*, Final Report (Nov. 19, 2004).

Harvard/Harris National survey agreed that DTC advertising increases patient compliance.¹⁸ Data submitted at the recent public hearing also indicate that DTC advertisements remind consumers to take their medication.¹⁹ The high costs and poor patient outcomes associated with non-compliance underscore the significant public health benefit of tools that encourage compliance, including DTC advertising.²⁰

F. DTC Communications Do Not Lead To Inappropriate Prescribing Decisions

Claims that DTC advertising causes consumers to exert inappropriate pressure on physicians for advertised drugs they do not need lacks empirical foundation. According to FDA's studies, in 88% of cases in which patients asked about a drug, physicians determined that the person had the condition that the drug treated.²¹ Physicians in the same study reported that 91% of the time patients did not seek to influence their care in a way that would be harmful.²² Other studies report similar findings.²³

The vast majority of physicians do not feel that DTC advertising has pressured them to prescribe inappropriate medications—or, indeed, that it has pressured them to prescribe anything at all.²⁴ Most consumers who consult their physicians about an advertised drug are not even seeking a prescription for a specific advertised drug. Multiple studies indicate that patients want

¹⁸ J. S. Weissman, *et al.*, *Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising*, Health Affairs, W4-224 (April 28, 2004).

¹⁹ C. Winnicki, *Recent Sufferers: Exploring Patient Behavior from Discovery to Diagnosis* (Nov. 1, 2005), presentation available at: <http://www.fda.gov/cder/ddmac/dtc2005/Winnicki.PPT>

²⁰ See, e.g., S.D. Sullivan, *et al.*, *Noncompliance with medication regimens and subsequent hospitalizations: a literature analysis and cost of hospitalization estimate*, J. Res Pharm Econ. 1990: 2(2); 19-33 (estimating that 5.5% of hospitalizations result from drug noncompliance); P. A. Tabor, *et al.*, *Comply with Us: Improving Medication Adherence*, J. Phar Pract. 2004: 17;3:167-180.

²¹ FDA Physician Survey (2002).

²² FDA Physician Survey (2002).

²³ *Market Measures/Cozint* (in inquiries for drugs treating high cholesterol and mood/anxiety disorders, physicians reported that, in over 80% of cases, patients asked about medicines that were appropriate to them) <http://www.fda.gov/cder/ddmac/p6thumma/index.htm>.

²⁴ *FDA Physician Survey* (2002). 82% of physicians said that DTC ads did not create any problems for their interaction with patients; 91% said the patient did not try to influence the course of treatment in a way that would have been harmful; 48% of GPs and 58% of specialists felt “not at all” pressured to prescribe a specific brand name drug when asked about it; *NMA/COSHAR Physician Survey*. 61% did not feel additional pressure to justify their prescriptions based on patient requests; 89% said they had not changed their prescribing habits as a result of DTC ads.

information about an underlying condition and available treatment, and are far more likely to ask about therapy than for a specific drug.²⁵

Moreover, asking a physician about a drug does not guarantee a prescription. According to a General Accounting Office report, of the 61.1 million people (33 percent of adults) who had discussions with their physician as a result of a DTC advertisement in 2001, only about 8.5 million (5 percent of adults) actually received a prescription for the product, a small percentage of the total volume of prescriptions dispensed.²⁶

III. The PhRMA Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines

PhRMA and its member companies have long understood the special relationship we have with the patients that use our innovative medicines. Despite the very positive role DTC advertising plays in educating patients about health issues and options, over the years, we have heard the concerns expressed about DTC advertising – that some ads may oversell benefits and undersell risks; that some ads may lead to inappropriate prescribing; that some patients may not be able to afford the advertised medicines; and that some ads may not be appropriate for some audiences. Some doctors have also complained that drug companies launch advertising campaigns without helping to educate doctors in advance.

Although actual practice and data on the effects of DTC advertising differ from these concerns, PhRMA recognized that the procedures and policies related to DTC advertising could be further enhanced. Accordingly, on July 29, 2005, PhRMA's Board of Directors unanimously approved *Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines* (see Appendix A). These 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 expressed about DTC advertising over the past few years. As a result, the Guiding Principles address many of the issues raised in FDA's September 13, 2005 request for comments.

The Guiding Principles, which went into effect in January 2006, are intended to ensure that DTC advertising continues to provide accurate, accessible, and useful health information that encourages the appropriate use of pharmaceuticals. To that end, the Guiding Principles

²⁵ *FDA Physician Survey* (2002). 23% of those surveyed asked their physicians about treatment for a condition, while only 7% asked about a specific brand); Henry N. Young, Ph.D., et al., *Does Direct-to-Consumer Advertising (DCTA) Promote Shared Decision Making? A Preliminary Study*, (Sept. 22, 2003) (93.5% of respondents were more likely to seek additional information about advertised drugs than a prescription); *NCL Patient Survey* (half of patients who visited a physician after seeing an ad said they wanted to find out if the medication was right for them, 33% said they wanted to find the best way to treat their condition, and only 10% said they wanted the advertised drug); *COSHAR Patient Survey* (21% of patients wanted to discuss a specific drug with their physician after seeing a DTC ad, but only 11% planned to ask for a specific prescription).

²⁶ General Accounting Office, *FDA Oversight of Direct-to-Consumer Advertising Has Limitations* (Washington, DC: GAO, October 2002).

reiterate signatory companies' longstanding commitment to developing DTC communications in accordance with all FDA requirements.

The Guiding Principles recognize that FDA regulations already set an extremely high standard for DTC advertisements for pharmaceutical products – higher than the standards applicable to the advertising of virtually any other product. According to FDA's regulations, all DTC information must be accurate and not misleading, can make product claims only when supported by substantial evidence; must reflect a balance between risks and benefits; and must be consistent with the FDA approved labeling. PhRMA companies are committed to meeting these existing high standards, and the Guiding Principles reiterate that commitment.

But the Guiding Principles go beyond existing regulatory requirements in order to promote an educated dialogue between physicians and patients. Our principles recognize that at the heart of our companies' DTC communication efforts is patient education. This means that DTC communications designed to market a medicine should responsibly educate patients about a medicine, including the conditions for which it may be prescribed. DTC advertising should also foster responsible communications between patients and health care professionals to help the patient achieve better health and a better appreciation of a medicine's known benefits and risks.

For example, the Guiding Principles state that signatory companies should spend appropriate time educating health care professionals about a new medicine before it is advertised to patients. This will help ensure that physicians know about a medicine first so that they are prepared to discuss the appropriateness of a given medication with a patient.

In addition, companies that sign onto these Guiding Principles agree to submit all new DTC television ads to the FDA before releasing them for broadcast. This commitment also goes beyond existing regulatory requirements, which merely require companies to submit their DTC television advertisements to FDA at the time they are first aired. This additional lead time should provide the Agency an opportunity to review new TV ads before they are aired, consistent with its priorities and resources. It also should provide FDA and sponsors a better opportunity to communicate expectations and identify and address issues before a DTC advertisement is viewed by the public.

The Guiding Principles also state that DTC television advertisements that identify a product by name should clearly state its approved indications and major risks. Critics contend that reminder ads on television often leave patients guessing about the nature of the advertised product, its intended use, and whether the patient should follow up with his or her physician. While PhRMA believes that reminder ads can help familiarize consumers with product names, we also believe that television ads should facilitate a more informed dialogue between patients and healthcare providers. To achieve this goal, the Guiding Principles call for signatory companies to provide appropriate benefit and risk information when a product is named in a television ad.

The Guiding Principles also go beyond existing legal requirements by asking signatory companies to focus more closely on the intended audience. As a result of concerns that certain prescription drug ads may not be suitable for all viewing audiences, the Guiding Principles state that, “DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved.” If an advertisement contains content that may be inappropriate for children, the advertisement should be targeted to predominantly adult audiences. This means programs or publications that are reasonably expected to draw an audience of approximately 80 percent adults 18 years or older.

The Guiding Principles contain many other important provisions intended to further enhance the value of DTC communications. For instance, should new and reliable information concerning a serious previously unknown safety risk be discovered, signatory companies commit to work with FDA to “responsibly alter or discontinue a DTC advertising campaign.” In addition, the Principles encourage companies to include, where feasible, information about help for the uninsured and underinsured. PhRMA member companies offer many programs that assist needy patients with their medicines, and DTC ads can be an effective tool to alert patients to these programs. The Principles also recognize that ads should respect the seriousness of the health condition and medicine being advertised and that ads employing humor or entertainment may not be appropriate in all instances.

Although the Guiding Principles are voluntary, consistent with PhRMA’s status as a voluntary trade association, the vast majority of PhRMA member companies – twenty-seven – have publicly stated their intention to follow the Guiding Principles. These companies are committed to establishing their own internal processes to ensure compliance with the Guiding Principles and to distribute the Guiding Principles internally and to advertising agencies. In addition, PhRMA’s Board of Directors unanimously approved the creation of an office of accountability to ensure the public also has an opportunity to comment. The office of accountability will receive comments from both the general public and healthcare professionals regarding DTC ads aired by signatory companies. The office of accountability will provide comments that are reasonably related to compliance with the Guiding Principles to the advertising company, and will issue periodic, publicly available reports concerning the comments and associated company responses. Each report will also be submitted to the FDA.

PhRMA’s Board also agreed to select an independent panel of outside experts and individuals to review reports from the office of accountability after one year and evaluate overall trends in the industry as they relate to the Guiding Principles. The panel will be empowered to make recommendations in accordance with the Principles.

PhRMA believes that the Guiding Principles are a responsible step toward improving DTC communications. Patients today are seeking more information about medical problems and potential treatments. Our Guiding Principles help ensure that DTC promotion facilitates thoughtful and informed conversations between patients and their healthcare providers.

IV. PhRMA Responses to FDA's Specific Questions

The following provides PhRMA's responses to specific questions raised by FDA in its September 13, 2005 Federal Register notice.

A. Educational Content and Reminder Ads

In its Federal Register notice, FDA asks whether greater focus on the educational component of an advertisement (i.e., devoting more attention to defining the disease and its manifestations) would benefit consumers. In PhRMA's view, DTC advertisements should serve to educate patients about a particular drug product, including the disease it is intended to treat and its risks and benefits. PhRMA's Guiding Principles, in fact, state that DTC advertising should be "designed to responsibly educate the consumer about [the advertised] medicine and, where appropriate, the condition for which it may be prescribed." Further, advertising should include information about the availability of other options, such as diet or lifestyle changes, when appropriate for the advertised condition.

Because of limitations associated with print and broadcast media, however, DTC advertisements cannot and should not replace the healthcare professional as the most authoritative source of information about the benefits and risks of a particular drug product for a particular patient. While DTC advertisements can and should provide educational content, a key goal of DTC should be to encourage patients to begin a dialogue with their physicians about their medical conditions and treatment options.

PhRMA, therefore, cautions against any effort by FDA to regulate the "educational content" of DTC advertisements. While PhRMA supports including an educational component in DTC advertisements, as evidenced by our Guiding Principles, PhRMA believes it will be exceedingly difficult to establish regulatory standards for a concept as subjective and amorphous as "educational content." Accordingly, FDA should continue to encourage greater focus on the educational component of DTC advertisements but should refrain from attempting to establish explicit regulatory standards.

With respect to FDA's related question about the role of reminder ads, PhRMA notes that the Guiding Principles address this issue by stating that DTC television ads that identify a product by name should also clearly identify its approved indications and major risks. The PhRMA Principles focuses on DTC television ads (as opposed to print ads) because these have been the primary focus of controversy and discussion. PhRMA believes that its voluntary Principles should help facilitate a more informed dialogue between patients and healthcare providers by presenting appropriate benefit and risk information whenever a product is named in a television ad.

B. Benefit and Risk Communication

In its Federal Register notice, FDA seeks feedback addressing consumer comprehension of benefit and risk information communicated in DTC advertisements. In particular, FDA requests comments on “why consumers and healthcare providers may believe that risk information is not being communicated as clearly as benefit information, even though that information is present [in DTC ads].”

As an initial matter, it is important to stress – as FDA does – that relevant risk information already is present in compliant full-product advertisements. Indeed, FDA’s existing regulations and oversight have been extremely effective at ensuring that the vast majority of DTC advertisements present truthful, accurate, well-balanced and useful healthcare information to patients, including all required risk information. The issue, therefore, is not getting companies to comply with existing requirements, which they already are doing, but rather ensuring that applicable requirements help facilitate consumer comprehension.

One reason for the perceived disparity in patient comprehension between risk information and benefit information may be that risk information is inherently more complex than benefit information. DTC ads (and, for that matter, approved package inserts) typically contain a single message about benefit (e.g., “Drug X treats Disease Y) but, by regulation, must contain a multitude of messages about the various risks and adverse events associated with the advertised drug product. Moreover, consumers often already are familiar with the benefit being discussed, since it is usually tied to a well-known and identifiable disease or condition (e.g., hay fever, depression), but may be less familiar with the risks, adverse events and possible drug interactions associated with the product (e.g., “don’t take Drug Y if you’re already taking an MAO inhibitor”). For these reasons, communication of risk information may always be more challenging than communication of benefit/indication information.

The goal of DTC communication, however, is not to turn consumers into medical experts. Rather, it is to spur communication between patients and physicians and to provide enough information about benefits and risks to facilitate an informed dialogue. Prescription drugs are complex and require the expert advice and oversight of a trained healthcare professional. DTC ads should not be regarded as a substitute for this expert advice and consultation. PhRMA believes that DTC advertising should clearly communicate that there are meaningful risks associated with the advertised product but should not be expected to fully educate patients about each specific risk. In this regard, as many experts testified at the public hearing, it may be more effective for DTC advertisements to focus on a few of the most important risks than to recite a laundry list of all possible risks from the package insert.

PhRMA strongly supports efforts to improve consumer comprehension of risk information, and accordingly, the Guiding Principles provide for a balanced presentation of risks and benefits, with risk information presented in clear, understandable language, without distraction from content, and in a manner that supports further dialogue between patient and

physician. PhRMA's Guiding Principles further elaborate that risk information should be presented in a way that facilitates patient comprehension. With respect to television advertising, the Guiding Principles state that the video and audio presentation of risk information should be similar in terms of prominence and clarity to the visual and audio presentation of other information about the product. PhRMA believes that ads developed in accordance with the Guiding Principles will help reduce any disparity in consumer comprehension of benefit and risk information. FDA's proposed revisions to the brief summary requirement in print ads also should help address this issue if implemented carefully (as discussed in more detail in Section IV.G below).

C. Target Audience

The September 13, 2005 Federal Register notice requests comments on whether the Agency should take the population targeted by DTC promotion into account as it considers the regulatory framework for DTC promotion. PhRMA does not believe it is necessary or practical for FDA to apply different advertising standards to DTC ads targeted to different subpopulations. First, PhRMA is not aware of any evidence suggesting that ads targeted to one subset of the population or patient group have caused unique problems. Second, such an approach would create significant practical problems since it would be difficult or impossible for FDA to (a) define relevant subpopulations that merit special or different treatment; (b) formulate special standards applicable to the specified subpopulation, and (c) determine for any particular advertisement whether the manufacturer "intended to target" a particular subpopulation. PhRMA believes that existing regulatory standards are adequate to protect all patient subpopulations against false or misleading DTC advertising.

Although PhRMA does not support the application of differing promotional standards to different target audiences, PhRMA does recognize that some prescription drug ads may not be suitable for all viewing audiences. Consequently, PhRMA's Guiding Principles state that "DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved." PhRMA believes that DTC advertising is important even for the health conditions that may be embarrassing or sensitive. By the same token, PhRMA and its member companies recognize that these ads should be disseminated with sensitivity and respect to the feelings of parents and children.

D. Coupons, Free Samples, Free Trials, and Money-back Guarantees

The Agency also specifically invited comments on the use of coupons, free samples, free trials, and money back guarantees. PhRMA believes that these tools have many benefits and should remain available as part of responsible DTC promotional practices. Free samples, for instance, permit physicians and patients to become acquainted with a drug product with no obligation to continue using it for an extended period of time. Free samples also allow physicians to test several medications in a class to determine which works best for a particular patient. These types of tools thus often enhance patient care.

Moreover, these promotional tools already are subject to stringent regulatory oversight under a variety of state and federal laws. For example, drug samples must be distributed in accordance with the strictures of the Prescription Drug Marketing Act, which specifies labeling, acceptable distribution channels and recordkeeping requirements. Likewise, samples, coupons, free trials, money back guarantees and other promotional tools are subject to federal and state laws, which may include anti-kickback laws; state “all-payer” laws; consumer protection laws; generic substitution laws; and a multitude of other state and federal requirements. As long as use of these tools complies with all applicable laws, and associated promotional materials meet relevant FDA requirements, the use of coupons, free samples and similar tools should not be restricted.

PhRMA acknowledges that promotional tools have on occasion been used inappropriately. Such situations, however, are rare and most appropriately addressed on an individual basis. Rather than imposing special restrictions or requirements on the use of coupons, free samples, free trials, guarantees, and other similar tools, PhRMA urges FDA to continue to evaluate their use on a case-by-case basis. At a minimum, FDA should base any proposals for regulatory reform on empirical evidence demonstrating that such reforms will address identified, widespread problems with tools such as samples and coupons.²⁷

E. Testimonials/Endorsements

The September 13, 2005 Federal Register notice also sought comment on the use of testimonials from consumers/patients or from healthcare providers. PhRMA believes that testimonials and endorsements are appropriate forms of promotion, provided that the advertisement complies with FDA’s regulatory requirements and is fully substantiated. In particular, PhRMA believes that (a) testimonials should not contain any representations which would be deceptive, or could not be substantiated, if made directly by the advertiser; and (b) persons providing testimonials should be *bona fide* users of the product.²⁸ These requirements are consistent with the principles enunciated in the Federal Trade Commission’s (“FTC”) Guide Concerning Use of Endorsements and Testimonials in Advertising, *see* 16 C.F.R. Part 255.

The FTC considered adopting a prohibition on consumer endorsements of drug products, but ultimately determined that a ban was unnecessary, so long as certain limitations were imposed. *Endorsements and Testimonials in Advertising; Promulgation of Final Guides Concerning Use*, 45 Fed. Reg. 3870, 3871 (Jan. 18, 1980). These limitations are incorporated into the final Guide as follows: “[c]laims concerning the efficacy of any drug or device as defined in the Federal Trade Commission Act, 15 U.S.C. 55, shall not be made in lay endorsements unless (1) the advertiser has adequate scientific substantiation for such claims and

²⁷ PhRMA notes that FDA issued a Federal Register notice earlier this year announcing a study on the impact of coupons on consumer perceptions of risks and benefits. 71 Fed. Reg. 6077 (Feb. 6, 2006). The link to that notice subsequently was removed from FDA’s website, however, and the status of the study is not clear.

²⁸ This last requirement, however, should not prohibit the use of actors or fictionalized situations in DTC advertisements.

(2) the claims are not inconsistent with any determination that has been made by the Food and Drug Administration with respect to the drug or device that is the subject of the claim.” 16 C.F.R. §255.2(c).

PhRMA believes that compliance with existing FDA requirements and the above factors (which are consistent with the FTC Guide) will ensure that any use of testimonials in pharmaceutical advertising will be truthful and not misleading.

Finally, PhRMA believes that the use of celebrity endorsers in DTC advertisements is appropriate and should not be subject to special requirements. Research demonstrates that, on average, celebrity DTC ads are more likely than other advertisements to gain viewer attention and break through the clutter of other advertisements.²⁹ As a result, celebrity advertisements may be more effective at motivating patients to visit a healthcare practitioner, a conclusion suggested by some of the research, at least for some conditions (e.g., migraine). Moreover, there is no evidence that celebrity endorsements create problems regarding the communication of risks and benefits. PhRMA thus believes that celebrity endorsements should be subject to the same requirements as other DTC advertisements.

F. Comparative Advertising

PhRMA believes that comparative DTC ads are appropriate and useful to consumers, provided that the comparative claims are adequately substantiated and the ads comply with all other FDA requirements. PhRMA believes it would be inappropriate for the Agency to apply different standards to an ad, depending upon whether it included comparative claims, and instead recommends that compliance with FDA requirements continue to be assessed on a case-by-case basis.

G. Improving Communication of Benefits and Risks in the Brief Summary in DTC Print Advertisements

The existing regulatory structure governing DTC communications has been extremely effective at ensuring that the vast majority of DTC advertisements present truthful, accurate, well-balanced and useful healthcare information to patients. Nevertheless, PhRMA acknowledges that carefully targeted revisions may be appropriate, particularly to improve the communication of benefits and risks in DTC advertising.

On February 10, 2004, FDA issued a draft guidance document seeking to make the risk information provided in DTC print advertisements more accessible to consumers by encouraging manufacturers (a) to present information only about the most serious and/or most common risks, and (b) to use consumer-friendly language. PhRMA strongly supports the underlying goal of FDA's Brief Summary Guidance to increase the effectiveness of risk communications to

²⁹ Testimony of Abhilasha Mehta, Ph.D., Gallup & Robinson, Inc., before the Food and Drug Administration, Public Hearing on Direct-to-Consumer Promotion of Medical Products, November 1, 2005.

patients. However, as discussed in our prior comments on the draft guidance document,³⁰ which are incorporated herein by reference, PhRMA urges FDA to accomplish this goal in a way that does not create unnecessary product liability concerns.

The Draft Guidance provides two alternative methods for making necessarily complex risk information more accessible to consumers: (1) reproducing “FDA-approved patient labeling, either in its entirety or as modified to omit less important risk information,” or (2) providing the risk information that would be appropriate for the FDA-approved “Highlights” section of the package insert pursuant to FDA’s proposed regulation on the content and format of prescription drug labeling. *See* 65 Fed. Reg. 81082 (Dec. 22, 2000). While these alternatives would not necessarily provide information about each specific risk associated with a product, they would provide information about the product’s most serious risks and less serious, but most frequently occurring, adverse events. Moreover, FDA encourages manufacturers to present this risk information in consumer-friendly language rather than precise medical terminology in order to enhance comprehension by lay readers.

Although PhRMA strongly supports FDA’s efforts to enhance the clarity and usefulness of risk information presented in DTC communications, we are concerned that the alternatives proposed by FDA will not effectively address the problem due to the potential impact on product liability litigation. The two alternatives proposed by FDA are, in fact, framed as an exercise of FDA’s enforcement discretion. For instance, rather than stating that these alternatives comply with the brief summary requirements, FDA states that it “does not intend to object” to the use of these alternatives, even though the information provided would not include each specific risk mentioned in the FDA-approved professional labeling. This language could potentially be interpreted to suggest that the proposed alternatives do *not* meet the requirements of FDA’s existing regulations (21 C.F.R. §202.1(e)(3)(iii)), but that FDA nevertheless will exercise its enforcement discretion in the interest of enhanced consumer comprehension.

This ambiguity places manufacturers in an untenable position. Because omitting any risk information could potentially be interpreted as violating FDA’s regulations, manufacturers could face greater exposure to negligence claims based upon a failure to warn theory. Indeed, in many jurisdictions, the failure to comply with FDA regulations can be used as *prima facie* evidence that the manufacturer was negligent. *See* Restatement (Second) of Torts § 286.

Overall, PhRMA believes that FDA’s proposal is extremely valuable and should be implemented. The proposal must be implemented, however, in a manner that benefits patients without subjecting manufacturers to potentially increased liability risks. In order to accomplish this, FDA should: (a) revise its brief summary regulations to explicitly permit these alternative presentations of risk information, and abandon the current plan to implement them through a Guidance document announcing an exercise of enforcement discretion, or (b) clarify that the alternatives provided in the Draft Guidance comply with FDA’s brief summary regulations, and

³⁰ *See* May 10, 2004 submission to Docket No. 2004D-0042.

also (c) mandate the precise contents of the brief summary for a particular product, and provide that FDA's determination on the content of the brief summary preempts conflicting or contrary state law, regulations, or court decisions for purposes of product liability litigation. Indeed, FDA recently announced its position that approved drug labeling preempts contrary state product liability claims.³¹ The same factors that inform that decision also apply in this case.

Although FDA's regulations potentially could be interpreted to require disclosure of "each specific side effect and contraindication," the FD&C Act does not require this level of detail. The statute instead gives FDA broad authority to designate, by regulation, the contents of the brief summary. 21 U.S.C. § 352(n) ("such information in brief summary relating to side effects, contraindications, and effectiveness as *shall be required in regulations ...*") (emphasis added). FDA thus has ample authority to revise its brief summary regulations to allow manufacturers to provide streamlined, consumer-friendly risk information in DTC print advertisements rather than "each specific side effect and contraindication," as is currently required. *See* 21 C.F.R. § 202.1(e)(3)(iii). This not only would bring the "brief summary" closer to something that truly is "brief" and a "summary," but also would avoid creating a Catch-22 situation for manufacturers.

PhRMA emphasizes, however, that while revising or clarifying the regulations and Draft Guidance, as set forth above, would eliminate the Catch-22 situation, it still might expose pharmaceutical manufacturers to meaningful product liability risks. Suits would inevitably arise based on the alleged inadequacy of the streamlined risk information and purported inconsistencies between the condensed information and the more comprehensive information contained in the approved package insert. These risks are far from speculative.

The best way to resolve these liability risks would be for FDA to mandate the precise contents of the brief summary for a particular product, and for FDA's determination to preempt conflicting or contrary state law, regulations, or court decisions for purposes of product liability litigation. Based upon the wealth of information presented in an NDA, experts within the Agency routinely determine the information necessary for practitioners as they consider whether to prescribe a specific drug product. Those same experts within the relevant Division and experts within DDMAC, in consultation with the sponsor, should mandate the language used in the brief summary.

In summary, PhRMA supports FDA's goal to increase the effectiveness of risk communications to patients, and urges the Agency to adopt the recommendations above to avoid creation of potential product liability issues for manufacturers that could interfere with achieving this goal.

³¹ 71 Fed. Reg. 3922, 3933 (January 24, 2006).

H. Improving Communication of Benefits and Risks in DTC Broadcast Advertisements

PhRMA believes that the existing FDA requirements applicable to broadcast advertising for prescription drugs are appropriate and reasonable, and compliance with those requirements results in advertising that is truthful and not misleading, and that motivates consumers to contact their doctors and engage in thoughtful dialogue about health concerns.

Although PhRMA does not support changing the existing regulatory requirements, PhRMA notes that many of the Guiding Principles are designed to further enhance the utility of broadcast advertising. For example, the Guiding Principles state that DTC television advertising that identifies a product by name should also identify the approved indication(s) and major risks associated with the product. The Guiding Principles also provide that risk and safety information should be presented in clear, understandable language, without distraction from content, and in a way that fosters more productive physician/patient encounters. As a final example, signatory companies will submit all new television advertisements to the FDA before they are broadcast, along with information on the first scheduled broadcast date, thus enabling FDA to express any concerns about an ad before it is broadcast to consumers.

I. New Communication Technologies

PhRMA believes that the existing FDA requirements applicable to new communication technologies, such as the Internet, are appropriate and reasonable and that compliance with those requirements results in advertising that is truthful and not misleading. As with other forms of DTC communications, advertising through new communication technologies must be accurate and not misleading, can make product claims only when supported by substantial evidence; must reflect a balance between risks and benefits; and must be consistent with the FDA approved labeling. PhRMA believes that these requirements are flexible enough to be adapted effectively to new communication technologies such as the Internet. PhRMA urges FDA to continue to apply these requirements in a flexible manner to new and emerging communication technologies.

J. Enforcement Tools

The Agency currently has a number of enforcement tools at its disposal, and routinely uses many of them to halt dissemination of violative promotional materials and to provide guidance on the appropriate content of future promotional materials.³² PhRMA believes these

³² Typically, FDA notifies a company through an untitled or Warning Letter that it believes that a particular promotional piece disseminated by a company is violative and requests appropriate corrective action. This usually results in a prompt and mutually satisfactory resolution of the issues presented in FDA's letter. However, in the case of particularly egregious violations, or when FDA and the company are unable to arrive at an agreed resolution, FDA can rely and has relied on more formal sanctions, including injunctions providing for pre-dissemination review and enhanced training.

existing enforcement tools are appropriate and effective. Indeed, the vast majority of DTC advertising is fully compliant with existing requirements and provides accurate, balanced and useful information about benefits and risks.

PhRMA also believes that many violative situations can be avoided through increased communication between sponsors and FDA. Even though pre-submission is not required, manufacturers often seek FDA feedback on broadcast and other advertisements prior to dissemination, a practice that is encouraged by FDA. PhRMA expects this practice will become more common following implementation of the Guiding Principles, which encourage manufacturers to submit all new DTC television advertisements to FDA before releasing them for broadcast. This additional lead time should provide the Agency an opportunity to review new television ads before they are aired – consistent with its priorities and responsibilities. It also should provide FDA and sponsors a better opportunity to communicate expectations and identify and address issues *before* a DTC ad is viewed by the public. This, in turn, should reduce the need for post-dissemination enforcement.

V. Revisions To The Current Regulatory Structure Should Be Data Driven and Supported By Consumer Research

PhRMA believes it is essential to utilize an evidence-based approach when addressing all of the questions raised in FDA's September 13, 2005 request for comments. As discussed above, research indicates that DTC promotion developed under the current regulatory scheme helps educate patients about medical conditions and treatment options, encourages a thoughtful dialogue between patients and physicians, prompts large numbers of Americans to discuss illnesses with their physicians for the first time, including undertreated/underdiagnosed conditions, and promotes improved compliance with physician-prescribed treatments and concomitant savings in healthcare costs. Because compliance with current regulatory requirements has resulted in useful, informative DTC promotion, it is critical that these requirements not be changed in the absence of data establishing that the changes would further enhance the value of DTC promotion.

New proposed approaches should be data-driven, *i.e.*, supported by rigorous consumer research demonstrating increased consumer comprehension. Multiple formats should be evaluated to identify the most beneficial and effective method(s) possible to promote consumer retention and comprehension of the information. In short, PhRMA firmly believes that the best way to communicate risk and other information can only be determined through rigorous consumer research methods which analyze a wide range of both traditional and non-traditional methods of communication, and we therefore urge FDA to rely on such research, as it has previously, in similar situations where consumer comprehension is critical.³³

³³ *E.g.*, in connection with development of Drug Facts labeling.

VI. First Amendment Protection Applies To DTC Promotion

Any proposed revisions to the current regulatory system for DTC communications must be consistent with the free speech protections of the First Amendment to the United States Constitution.

When the FDA restricts the speech of pharmaceutical manufacturers and other regulated entities, the restrictions are subject to scrutiny under the First Amendment to the United States Constitution. Recent decisions of the Supreme Court and other federal courts confirm that such restrictions cannot be justified as merely incidental to FDA's regulation of conduct, or automatically authorized by FDA's public health mandate. Of course, speech that is false, misleading, or proposes an otherwise unlawful transaction is not protected. However, in order to justify limitations on truthful, non-misleading speech about lawful products and activities – such as DTC promotion of approved drug products developed in accordance with FDA's existing regulations – the Agency must show that the ends served and the means employed are legitimate and appropriately circumscribed.³⁴

DTC promotion – like other forms of advertising and promotion – is commercial speech and is protected by the First Amendment. Any restriction on DTC promotion must therefore satisfy the well-known *Central Hudson* test in order to pass constitutional muster. *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). The First Amendment protects commercial speech because the speech “assists consumers and furthers the societal interest in the fullest possible dissemination of information.” *Id.* at 561-62.

Under *Central Hudson*, the initial inquiry is whether the speech at issue proposes a lawful transaction and is not misleading. *Central Hudson*, 447 U.S. at 563. Regulations that effectively ban truthful, nonmisleading commercial speech about a lawful product “hinder consumer choice [and] impede debate over central issues of public policy” and, therefore, “rarely survive constitutional scrutiny.” *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503, 504 (1996).

It is clearly established that “FDA may not restrict speech based [simply] on its perception that the speech could, may, or might mislead.” *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81, 81 (D.D.C. 1999). Rather, FDA must put forth concrete proof that the restricted speech is actually or inherently misleading. *Ibanez v. Florida Dept. of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994) (government's burden is not satisfied by “rote invocation of the words ‘potentially misleading’”); *see also Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) (the government's “burden is not satisfied by mere speculation or conjecture”).

³⁴ PhRMA submitted extensive comments in response to the Agency's request for comments on First Amendment issues. We refer the Agency to this September 13, 2002 submission to Docket No. 2002N-0209 for a more comprehensive discussion of PhRMA's views on this important subject.

If speech concerns a lawful activity, and the Agency cannot make a record establishing that the speech is in fact misleading, then the Agency must satisfy the three remaining prongs of the *Central Hudson* inquiry in order to justify a restriction on the speech. Specifically, the restriction must: (1) promote a substantial governmental interest; (2) directly advance that interest; and (3) be no more extensive than necessary to achieve the asserted government interest. *Central Hudson*, 447 U.S. at 566. Because the government generally has an undeniable interest in protecting the health and safety of its citizens, the constitutionality of FDA-imposed limitations on non-misleading speech typically turns, first, on whether the action directly advances the asserted government interest, and, second, on whether the government's legitimate interests could be served in a less restrictive way.

To demonstrate that a limitation on speech directly advances a government interest, the government "bears the burden of showing not merely that its [action] will advance its interest, but also that it will do so to a material degree." *44 Liquormart*, 517 U.S. at 505 (internal quotation and citation omitted). The government must prove that "the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71.

To satisfy the final element of *Central Hudson*, agency action that abridges speech must not be more extensive than necessary to serve the government's legitimate interests. *Thompson v. Western States Medical Center*, 535 U.S. 357, 371 (2002). A restriction is not appropriately tailored if "there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech." *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n. 13. "[I]f the government can achieve its interests in a manner that does not restrict speech or that restricts less speech, the Government must do so." *Western States*, 535 U.S. at 371.

To date, FDA has not imposed any special restrictions on DTC promotion, but the September 13, 2005 request for comments suggests that FDA may be reconsidering this approach. Moreover, various proposals to restrict DTC promotion have surfaced in the last several years, some of which were discussed during the November 2005 public hearing on DTC promotion. Strong policy and legal reasons militate against adoption of any special restrictions on DTC advertising. Subject to the comments in Section IV.G above on the brief summary draft guidance, PhRMA believes that FDA's current policies on DTC advertising of prescription drugs, as reflected in its regulations and guidance documents, provide a workable approach without undue or impermissible restriction of speech, and should remain in effect.

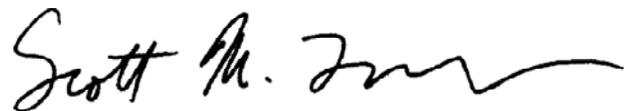
FDA has a constitutional obligation to ensure that it acts in accordance with the First Amendment, and therefore any changes to the current regulatory scheme under consideration must be carefully scrutinized under the First Amendment.

VI. Conclusion

As patients participate to a greater degree in decisions concerning their healthcare, DTC advertising helps meet consumer demand for information about health conditions and possible treatments. Information empowers consumers to effectively partner with their healthcare providers to make optimal decisions about their healthcare. DTC advertising also serves a valuable role in educating patients about the limitations and risks associated with certain therapies. DTC advertising cannot and should not replace the healthcare professional as the most authoritative source for obtaining information about the risks and benefits of a particular drug product for a particular patient. However, DTC advertising can encourage patients to talk with their physicians about their medical conditions and treatment options, which, in turn, translates into better and more cost-efficient healthcare.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott M. Lassman". The signature is fluid and cursive, with a long horizontal flourish at the end.

Scott M. Lassman
Assistant General Counsel

Appendix A

**PhRMA Guiding Principles
Direct to Consumer Advertisements
About Prescription Medicines**

PhRMA

PhRMA Guiding Principles Direct to Consumer Advertisements About Prescription Medicines

Preamble

Given the progress that continues to be made in society's battle against disease, patients are seeking more information about medical problems and potential treatments so they can better understand their health care options and communicate effectively with their physicians. An important benefit of direct-to-consumer (DTC) advertising is that it fosters an informed conversation about health, disease and treatments between patients and their health care practitioners.

A strong empirical record demonstrates that DTC communications about prescription medicines serve 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.

The Pharmaceutical Research and Manufacturers of America (PhRMA), represents America's leading pharmaceutical research and biotechnology companies. As the companies responsible for developing new and innovative medicines, PhRMA members want patients and consumers to talk to their physicians about the medicines that may help them and to fully understand the known risks regarding these medicines. We know that DTC communications, particularly DTC television advertising, can be a powerful tool for reaching and educating millions of people, and we are committed to ensuring that our DTC communications provide accurate, accessible and useful health information to patients and consumers. DTC advertising of such important and powerful products as prescription drugs should be responsibly designed to achieve these goals and to encourage the appropriate use of these products.



First and foremost, we have a responsibility to ensure that our DTC communications comply with the regulations of the Food & Drug Administration (FDA). In general, the FDA requires all DTC information:

- To be accurate and not misleading;
- To make claims only when supported by substantial evidence;
- To reflect balance between risks and benefits; and
- To be consistent with the FDA-approved labeling.

The innovative pharmaceutical industry takes its responsibilities to comply with FDA requirements seriously. Companies devote substantial time and effort, and often ask for input from FDA, to ensure that DTC communications are accurate, fairly balanced and meet all applicable legal requirements. PhRMA member companies will engage in a dialogue with FDA to maximize opportunities for FDA review of DTC advertising prior to release, consistent with these principles and the agency's priorities and resources.

Beyond meeting their legal obligations, companies strive to deliver messages that fundamentally serve to educate patients and consumers and encourage them to seek guidance from their health care professionals.

To express the commitment of PhRMA members to deliver DTC communications that serve as valuable contributors to public health, PhRMA has established the following voluntary guiding principles.



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.

Accountability for the Guiding Principles

Companies commit to establishing internal processes to ensure compliance with these guiding principles. Companies also commit to distributing these guidelines internally and to their advertising agencies.

Each company's intentions with regard to these guiding principles will be made public.

PhRMA will establish an office of accountability that will be responsible for receiving comments from the general public and from health care professionals regarding DTC advertising conducted by any signatory company to these principles. Any company that publicly states that it will follow the principles will be considered a signatory company.

The PhRMA office of accountability will provide to the signatory company at issue any comment that is reasonably related to compliance with the principles.

The PhRMA 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.

One year after the effective date of the Principles, the PhRMA office of accountability will select an independent panel of credible individuals to review reports of that year, to track the overall trends in the industry as they relate to the Principles, and to make recommendations in accordance with the Principles. The panel's report will be included in the next report of the PhRMA office of accountability.



PhRMA Guiding Principles Direct to Consumer Advertisements About Prescription Medicines

Questions and Answers

Q: *What is meant by a “direct to consumer television advertisement” in the context of these principles?*

A: A direct to consumer television advertisement is a portion of television air time on broadcast or cable television that is bought by a company for the purpose of presenting information about one or more of the company’s medicines. A DTC television advertisement does not include sponsorship of activities.

Q: *What is meant by “direct to consumer print advertisement” in the context of these principles?*

A: A direct to consumer print advertisement is space that is bought by a company in newspaper or magazine publications targeted to patients or consumers, or a direct mail communication paid for and disseminated by a company to patients or consumers, for the purpose of presenting information about one or more of the company’s medicines. A DTC print advertisement does not include sponsorship of activities.

Q: *How long must a company wait under Principle 6 before advertising a new medicine after the medicine is approved by FDA?*

A: Principle 6 demonstrates the companies’ commitment to devote sufficient resources and time to health care professional education before launching a direct to consumer advertising campaign. Principle 6 ensures that health care professionals will have a reasonable opportunity to learn about new medications before their patients ask questions about them so they will have accurate, up-to-date information to use in responding to patients’ inquiries and guiding patients to the most appropriate treatment option. Establishing a single uniform waiting period for all companies and all medicines could have the unintended consequence of denying patients important information about new medicines, even after health care professionals have been well educated. Each company will decide for itself how best to implement an effective educational program, taking into account such factors as health care professionals’ knowledge of the condition being treated, the severity and/or prevalence of the condition, the novelty of the new treatment, and the complexity of the medicine’s risk-benefit profile and directions for use.



Q: *Does Principle 8 require companies to do more than what is already required under current FDA regulations?*

A: Yes. Current law provides that companies must submit their DTC television advertisements to FDA upon first use for FDA's review at its discretion. Under Principle 8, while not intending to place additional burdens on FDA, companies commit to submitting new DTC television advertisements to FDA earlier than currently required and a reasonable time in advance of first use to give FDA the opportunity to comment, consistent with its priorities and resources. Companies also commit to inform FDA when they submit an advertisement of the earliest date the advertisement is scheduled to air.

Q: *Should companies notify FDA if they are specifically requesting feedback on a particular advertisement submitted under Principle 8?*

A: In order to permit FDA to allocate its resources effectively, companies should notify FDA if they are specifically requesting feedback on a submitted DTC advertisement. Companies also should indicate whether the requested FDA review is time-sensitive to help FDA prioritize its review activities. As a general matter, we understand that FDA expects companies to submit the following information with the submitted DTC advertisement: (1) a statement indicating whether the company is submitting the advertisement for prior Agency review and feedback, or for the Agency's information; and (2) if feedback is requested, a statement identifying whether the company is requesting FDA review on a priority basis; (3) a brief description of the reasons for any request for priority review (e.g., identifying the basis for the submission and the nature of any change the company deems significant) and (4) the earliest date the company plans to finalize the advertisement. Companies typically should reserve a priority review request for those submissions that are most time-sensitive, keeping in mind that FDA may choose to review only one iteration of a particular new DTC advertisement on a priority basis.

Q: *PhRMA states that, under Principle 8, companies should submit new DTC television advertisements to the FDA a reasonable time before releasing the advertisement for broadcast to give FDA the opportunity to comment, consistent with its priorities and resources. What constitutes "a reasonable time" in this context?*

A: The precise time frame for submission of a particular DTC advertisement will vary depending on the advertisement in question and purpose of the submission. If a company is specifically requesting feedback from FDA, either by priority review or standard review, it should submit the DTC advertisement far enough in advance to permit the Agency to perform the requested review. Although the timing of FDA's review of DTC advertisements will be dictated by the Agency's priorities and resources, a company seeking priority review will maximize its opportunity to receive



comments from the Agency if the company allows 30 calendar days for FDA review and comment. A company seeking non-priority review for a particular advertisement should try to allow more than 30 calendar days for FDA review, while less lead time could be appropriate if a company is submitting a particular advertisement for the Agency's information.

Q: *Does Principle 8 require companies to submit a new DTC television advertisement to FDA in advance, even if the advertisement reflects only minor changes to a previously submitted advertisement?*

A: No. Under Principle 8, companies should submit only new television advertisements or advertisements that have been changed in a way that the companies believe is significant. For instance, where a company changes an existing advertisement—possibly by changing a telephone number listed on the screen or by replacing an actor—to use for a different targeted audience, but does not substantially change the advertisement's script or theme, then the company is not required under Principle 8 to submit the changed advertisement to FDA. However, where a company changes an advertisement so that the benefit and/or risk information is presented in a different way, the company likely has made a significant change, and the advertisement should be submitted to FDA. Other circumstances that typically would trigger submission of DTC television advertisements under Principle 8 include (1) introduction of a new or never-before-advertised product; (2) new indications for existing products; (3) significant new risk information; (4) new comparative claims or patient outcome claims; or (5) new patient populations.

Q: *Does Principle 8 necessarily require a company to submit the final version of a new DTC television advertisement to FDA prior to releasing the advertisement for broadcast?*

A: No. The details of what will be submitted may be addressed in dialogue between companies and FDA.

Q: *Would additional dialogue between companies and the FDA be helpful as Principle 8 is implemented?*

A: Yes. Additional dialogue should occur to maximize opportunities for FDA review of DTC television advertising prior to release, consistent with this principle and the agency's priorities and resources.

Q: *Under Principles 3 and 9, does a company have to mention another medication that may also be appropriate for treating the advertised condition?*

A: No. These principles are intended to encourage companies to include in their advertisements information about therapeutic options and appropriate steps patients could take (which may or may not include other medicines), in consultation with health care professionals, to treat their disease or condition. This is consistent with the pharmaceutical industry's goal of helping patients achieve better overall health.

Q: *Is there only one right way to present risk information in advertisements?*

A: No. An advertisement will comply with Principle 11 if it presents information about the medicine's risks in a way that patients are reasonably likely to take in and understand this information. For television advertisements, the visual and audio presentation of risk information should be similar in terms of prominence and clarity to the visual and audio presentation of other information about the medicine. Of course, even the most informative advertisements can't provide information on all possible risks that may relate to each individual patient. Therefore, the conversation between a patient and a health care professional is critical to the patient's understanding of whether a medicine is right for that individual patient. DTC advertisements should motivate patients to ask their health care professionals for more information about a medicine's risks and benefits. These objectives can be achieved in a variety of ways, and each company will exercise its judgment consistent with FDA requirements.

Q: *What happens if a comment from the public about a company's DTC advertisement conflicts with recommendations or comments the company has received from FDA regarding the advertisement?*

A: The FDA has the authority to determine whether a particular advertisement is consistent with FDA regulations. If FDA chooses to give recommendations or comments on a particular DTC advertisement and the company follows those recommendations or comments, the company will be able to respond to any complaint regarding that aspect of the DTC advertisement that it complies with the PhRMA Principles by virtue of the fact that it followed FDA's recommendations.

Q: *Does Principle 12 suggest that all advertisements should be somber in tone and should not employ lightness, humor or entertainment?*

A: No. Principle 12 recognizes that health conditions and medical treatments are serious issues for patients. While humor or entertainment may not be appropriate in conveying all messages, they may be effective tools for attracting public attention to a particular disease or treatment, reducing any stigma associated with the condition, communicating educational messages about health conditions, and motivating patients to discuss those conditions openly with their health care providers.

Q: *What criteria should be applied to determine whether a company has complied with Principle 13 and targeted its advertising to avoid audiences that are not age appropriate for the messages in the advertisements?*

A: Advertisements containing content that may be inappropriate for children should be targeted to programs or publications that are reasonably expected to draw an audience of approximately 80 percent adults (18 years or older). Companies will be individually responsible for examining reliable, up-to-date audience composition data, to the extent that information is available, to determine whether a particular program or publication is reasonably likely to attract an audience that is age appropriate for a particular advertisement.

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