PhRMA Enhances Voluntary Guidelines on Direct-to-Consumer Advertising

On December 10, 2008, the Board of Directors of the Pharmaceutical Research and Manufacturers of America (PhRMA) adopted revisions to the *PhRMA Guiding Principles on Direct-to-Consumer Advertisements about Prescription Medicines*. The revised Guiding Principles, which will take effect in March 2009, will replace the original Guiding Principles that were made effective in 2006. Both the original and revised Guiding Principles share the premise that direct-to-consumer (DTC) advertising campaigns should be accurate, balanced, and helpful to consumers. The revised Guiding Principles, however, contain a number of modifications to strengthen companies' self-regulation of DTC advertisements. Companies that choose to comply with the revised principles will need to review and, in many cases, revise their DTC advertising policies and practices.

The most significant revisions to the Guiding Principles are described below.

1. Off-label Promotion. The original Guiding Principles provided that DTC advertisements should comply with FDA regulations, make claims only when supported by substantial evidence, contain fair balance between risk and benefit information, and be consistent with FDA-approved labeling. The revised Guiding Principles retain these tenets, but also explicitly state that DTC advertisements should not promote medicines for off-label uses.
2. Actors and Celebrity Endorsers. The revised Guiding Principles call for companies to acknowledge in an advertisement when actors are used to portray healthcare professionals or when healthcare professionals appearing in the advertisement have been compensated for their appearance. The revised Guiding Principles also provide that a DTC advertisement should not feature a celebrity endorser unless the endorsement is an accurate reflection of the celebrity's opinion or experience, and that companies should verify the basis of the endorser's statements. The original Guiding Principles contained no guidance on this subject.
3. Adverse Event Reporting Information. To comply with the Food and Drug Administration Amendments Act of 2007 (FDAAA), the revised Guiding Principles state that DTC print advertisements should provide FDA's Medwatch telephone number and website address for reporting adverse events and that DTC television advertisements should refer consumers to a print advertisement providing the MedWatch information or the company's toll-free telephone number.
4. Activity Before Launch of a New DTC Campaign. The original Guiding Principles indicated that companies should spend an appropriate amount of time to educate healthcare professionals about a new medicine or therapeutic indication before launching the first DTC campaign. The revised Guiding Principles expand this point, encouraging companies to individually establish specific periods of time before launching a DTC campaign. Similarly, the revised Guiding Principles also call for companies to seek feedback from healthcare professionals and patients during the development of a DTC advertisement campaign.
5. Restrictions for DTC Advertisements that Contain 'Adult-Oriented Content.' The Guiding Principles have historically provided that DTC advertisements, in terms of content and placement, should avoid audiences that

are not age-appropriate for the messages involved. This concept is expanded in the revised Guiding Principles, which state that advertisements inappropriate for children should be placed in programs or publications reasonably expected to draw an audience comprised of 90 percent adults.

6. Prominence of Risk and Safety Information. In part to reflect FDAAA provisions, the revised Guiding Principles state that risk and safety information should be presented with reasonably comparable prominence to benefit information and in a clear, conspicuous, and neutral manner that does not distract from the content of the advertisement. The revised Guiding Principles also encourage patient education and responsible dialogue between patients and healthcare professionals by indicating that DTC television advertisements should direct patients to other resources where risk and benefit information may be available.

These revisions to the Guiding Principles reflect the increasingly difficult environment for DTC advertising. One of the most vociferous critics of DTC advertising, Congressman Henry Waxman (D-CA), was recently elected chairman of the powerful House Energy and Commerce Committee. Representative Waxman has stated his belief that intense marketing initiatives immediately following FDA approval of a new drug can overwhelm the prescribers before the true safety profile of the drug is known. To address this perceived problem, Congressman Waxman is actively pushing for legislation granting FDA the authority to place a moratorium on DTC advertising on certain drugs during the first two years following marketing approval. Furthermore, congressional criticism of DTC advertising is not limited to pharmaceutical companies, as the DTC advertising practices of medical device companies have recently been subject to investigation by the Senate Special Committee on Aging.

Government enforcement authorities are also focusing increasingly on DTC advertising. For example, in a recent settlement regarding off-label marketing between Pfizer and various state attorneys general relating to the marketing of the non-steroidal anti-inflammatory drug Bextra, the company agreed to submit all DTC advertising to the FDA for pre-clearance. Independent of this settlement, several companies at their own initiative have implemented moratoria on the release of DTC advertising for new compounds or have taken other measures to ensure that their DTC advertising campaigns are accurate and valuable to patients.

Compliance with the revised Guiding Principles, while voluntary, will likely affect industry's relationship with government entities and may contribute to the maintenance of the public's trust because PhRMA will post on its website a list of all companies that have pledged to follow the Guiding Principles. To ensure compliance with the revised Guiding Principles, it will be critical for pharmaceutical companies to review all of the revisions as well as their policies and procedures in these areas.

If you have any questions about the revised Guiding Principles and their effect on your business activities, please do not hesitate to contact your regular Ropes & Gray attorney.