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CLIENT ALERT

PhRMA Adopts "Guiding Principles for Direct-to-Consumer Advertisements About Prescription Medicines"

On August 2, 2005, the Pharmaceutical Research and Manufacturers of America (PhRMA) published fifteen "Guiding Principles" to better educate patients and consumers about the risks and benefits of prescription drugs and to encourage them to seek guidance from healthcare professionals. The Principles respond to growing scrutiny of consumer-directed advertising, including concerns that some ads understate risks in relation to product benefits, and questions about effects on drug utilization and spending.

Nature of the Guiding Principles

Key themes of the Guiding Principles are: ensuring compliance with regulatory requirements, educating appropriate audiences about disease conditions and treatment options, enhancing the role of healthcare providers in therapeutic decisionmaking, and ensuring that promotional campaigns reflect up-to-date information throughout a product's lifecycle. A full listing of the PhRMA Guiding Principles is attached for your review. Notable elements include:

- **Balanced Presentation of Benefit and Risk Information.** Risk and safety information in direct-to-consumer (DTC) advertising should be presented in accurate, understandable language, without distracting content, and in a manner that supports dialogue between patients and healthcare professionals.

- **Pre-Use Submission of Television Ads to FDA.** Companies are encouraged to submit all new DTC television advertisements, as well as significant changes to previously-released ads, to the Food and Drug Administration (FDA) before they are disseminated for broadcast. (Current regulations require only submission at the time of first dissemination, although FDA historically has requested voluntary pre-submission of product launch materials. Legislation was introduced in the spring of 2005 to require pre-dissemination submission of DTC advertisements.) No advance length of time is recommended, but companies are advised to inform FDA of the earliest date an advertisement is expected to air.

- **Suggestion of Alternatives Treatments.** DTC advertising should note the availability of options such as diet and lifestyle changes when appropriate for an advertised condition. Companies are encouraged to promote health and disease awareness as part of their DTC campaigns.

- **No "Reminder" Ads.** DTC 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 it. (This would eliminate TV ads recommending that viewers "Ask a healthcare provider if Drug X [for an unspecified indication] is right for you.") Event sponsorships are excluded from this Guiding Principle.

- **Interplay of Healthcare Professional Promotion and DTC Advertising.** In

order to foster beneficial communications between patients and healthcare professionals, companies should spend an "appropriate" amount of time to educate health providers about a new medicine or a new indication before beginning the first DTC advertising campaign. No specific length of time is recommended, but companies should take into account the relative importance of informing patients about the availability of a new medicine, the complexity of the risk-benefit profile, and healthcare professionals' knowledge about the condition being treated. Some industry members have announced they will wait 6 months to one year before advertising new products directly to consumers. Consumer groups and Senate Majority Leader Bill Frist have called for a moratorium on DTC advertising during the first two years after a product's approval.

- **Target Audiences.** DTC television and print advertisements should be targeted, in terms of content and placement, to audiences that are age-appropriate for the products involved (for example, sexual health products should be advertised during programs or in publications reasonably expected to draw an audience of approximately 80 percent adults (18 years or older)).

Accountability Process

PhRMA intends to establish an accountability process to evaluate comments from the public and healthcare professionals concerning companies that publicly commit to follow the Guiding Principles. The accountability office will provide companies with comments that reasonably relate to compliance with the Principles; it will also periodically report to the public and to FDA about the nature of comments and company responses.

The PhRMA Guiding Principles take formal effect in January 2006. One year after implementation (i.e., in early 2007), PhRMA plans to convene an independent panel to review advertising compliance reports, track trends, and make recommendations in accordance with the Principles.

FDA Response

FDA Commissioner Lester Crawford has been quoted as "reserv[ing] judgment, but I think it's a step in the right direction." The agency announced on August 16, 2005 that it hopes to discuss during an upcoming series of public meetings how to "increase the public health benefits of direct-to-consumer advertising."

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If you have questions about prescription drug promotion, or would like additional information, please do not hesitate to contact one of the following:

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