



December 23, 2005

Documents Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket 2005N-0354

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Food and Drug Administration (FDA) on direct-to-consumer (DTC) promotion of regulated medical products, including prescription drugs, vaccines and medical devices. This letter supplements the Academy's comments presented at the FDA public meeting on November 2, 2005.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 4,800 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

The Academy discourages the use of consumer-directed advertising that promotes specific prescription drug products, but supports advertisements that educate the public about disease symptoms and available treatment options.

AMCP recognizes that the public has a personal interest in health care. Advertising that increases public awareness about disease symptoms, informs consumers about available treatment options and diagnostic procedures that may be of benefit, stimulates discussions between prescribers and patients, and encourages individuals to pursue healthier lifestyles can improve the health status of patients. It does this by encouraging consumers to become more proactive about their health in general, and by fostering constructive dialogue between patients and their providers regarding their care.

AMCP strongly discourages advertising aimed at consumers that promotes the use of specific prescription drug products. In general, such ads aim to increase a product's market share or create a new market for the product. Whether or not a prescription item is medically indicated for a given patient, DTC advertising of the product can create unwarranted patient demand. The ads can often be misleading, failing to sufficiently warn consumers about the potential risks of using the product and about alternative treatment options.

The impact that DTC print and electronic advertising have had on the demand for prescription drugs and the pricing of these drugs has been the subject of considerable

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debate -- even more so now because of the substantial increase in the amount of such advertising, growing from \$791 million in 1996 to an estimated \$3 billion in 2004.

The promotion and advertising of prescription drugs is regulated by the FDA under its statutory authority. The FDA's implementing regulations and its 1997 guidance contain specific requirements and explanations regarding the content of advertisements that promote prescription drugs.

The Academy believes the approach taken by the FDA's 1997 guidance, which for the first time permitted broadcast DTC advertising that specifically identifies a drug product by name, is largely responsible for the explosion in DTC advertising of prescription drugs. The guidance resulted in a shift from advertising, which until then was primarily informational, to advertising that is now primarily aimed at increasing a product's market share or creating a new market for the product. Further, the type of advertising that followed issuance of the 1997 guidance has often been misleading, because it has frequently failed to sufficiently warn consumers about the potential risks of using the product, typically does not inform them about alternative treatment options, and fails to provide information about cost issues.

The problem noted above is exacerbated by the limited authority the agency has to ensure compliance with its regulations and the 1997 guidance. When current requirements are not met, the FDA's only available option is to issue a regulatory letter requesting that the advertisement be withdrawn or revised. Under current statutory authority, the FDA is limited in its ability to expand its oversight of DTC advertising. The Academy has encouraged Congress to enact legislation requiring FDA to pre-approve DTC advertising of specific products to ensure that promotions are fair, not misleading and provide balanced information as to benefits and risks, granting enforcement authority to ensure compliance and authorizing the financial resources to support this activity.

In July 2005, Senate Majority Leader Bill Frist (R-TN) asked the Government Accountability Office (GAO) to review FDA oversight of prescription drug advertising, the pharmaceutical industry's spending on such advertising, and the apparent impact on utilization, health care spending, patient education and awareness. In a 2002 report,<sup>1</sup> the GAO concluded that:

- "DTC advertising appears to increase prescription drug spending and utilization. Drugs that are promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Most of the spending increase for heavily advertised drugs is the result of increased utilization, not price increases."
- "DTC advertising is concentrated among a small number of drugs for chronic conditions and many of these same drugs are also promoted to physicians, both

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<sup>1</sup> United States General Accounting Office Report to Congressional Requesters, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, October 2002.

factors that may lead to increased sales. To date, the few studies that have examined the effects of DTC spending on prescription drug spending and utilization have found that DTC advertising increases both. In addition, there is clear evidence from consumer surveys that DTC advertising encourages consumers to request prescriptions for specific brand-name drugs from their physicians and that some physicians provide the requested prescription."

- "FDA's oversight of DTC advertising is focused on advertisements that have the greatest exposure or the greatest potential to be misleading. Pharmaceutical companies comply with FDA's requests to cease dissemination of misleading DTC advertisements. However, some pharmaceutical companies have repeatedly disseminated misleading advertisements for the same drug, and pharmaceutical companies have failed to submit, or to submit in a timely manner, all newly disseminated advertisements to FDA for review."

Concern about DTC advertising has been raised as part of the drug safety debate with those calling for greater scrutiny focusing on what they argue are inappropriate prescriptions being written because of consumer response to what are characterized as a constant barrage of advertisements. While DTC advertising does not have a direct causal effect as to the safety of prescription drugs, it is of concern when looking at the overall picture of medication safety, especially if DTC advertising prompts patients to insist on taking a drug with a high risk side effect profile or for an off label condition.

In August 2005, the Pharmaceutical Research and Manufacturers of America (PhRMA) issued voluntary advertising guidelines ("PhRMA Guiding Principles: Direct-to-Consumer Advertisements About Prescription Medicines")<sup>2</sup> to encourage companies to discuss medication safety risks in clear, understandable language; target the proper patients for specific treatments; recommend that patients discuss medications with their physicians; submit all new DTC television advertisements to the FDA prior to releasing them for broadcast; and educate health professionals about new medicines or therapeutic indications before beginning the first advertising campaign. The reaction to these guidelines has been mixed; some are applauding PhRMA's initiative, while others note that while it may be an acceptable first step, it does not go far enough in setting enforceable standards.

The Academy of Managed Care Pharmacy supports changes that would result in a significantly improved and comprehensive program for FDA oversight of DTC advertising. Specifically, we support the idea that the Agency should have:

1. the express authority to mandate prior approval of DTC advertising
2. sufficient funding to enforce review of DTC advertising and pursuit of remedial actions determined to be necessary
3. oversee content of DTC advertising to ensure that it
  - focuses on raising awareness of disease and symptoms

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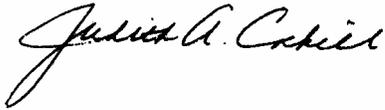
<sup>2</sup> Pharmaceutical Research and Manufacturers of America, *PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines*, August 2005.

- addresses alternative treatment options
- stimulates patient/provider dialogue, and
- encourages healthier lifestyles.

We look forward to working with the Agency and other public health authorities to protect patient health by ensuring appropriate advertising of medical products.

AMCP appreciates the opportunity to comment on this extremely important issue. If you have any questions, please contact me at (703) 683-8416 or at [jcahill@amcp.org](mailto:jcahill@amcp.org).

Sincerely,

A handwritten signature in black ink that reads "Judith A. Cahill". The signature is written in a cursive style with a large, sweeping initial "J".

Judith A. Cahill, CEBS  
Executive Director