



April 23, 2004

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

Re: Docket 2004D-0042

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Food and Drug Administration (FDA) on consumer-directed promotion of prescription drugs, specifically the brief summary guidance and the disease awareness guidance.

AMCP is a professional association of pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy through the application of managed care principles. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to over 200 million Americans served by managed care.

The Academy discourages the use of consumer-directed advertising that promotes specific prescription drug products, but supports ads 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, and encourages people to pursue healthy 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, direct-to-consumer advertising of the product can create unwarranted patient demand. The ads can often be misleading because they typically fail to warn consumers adequately about the potential risks of using the product, fail to inform them about alternative treatment options, and fail to provide information about cost issues. For more information on this position, please see the AMCP Position

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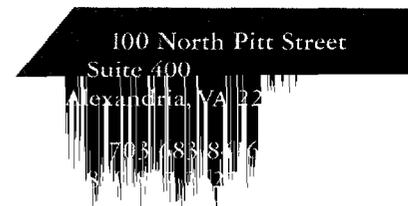
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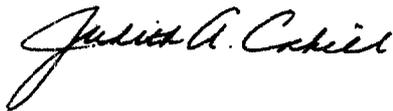
Statement on **Direct-to-Consumer Advertising** enclosed and available online at:
<http://www.amcp.org/amcp.ark?c=legislative&sc=position&id=4>.

Based on the above position, the Academy supports the FDA's draft guidance specific to the situation when disease awareness communication is presented in combination with reminder promotion or product claim promotion in a way that causes the audience to perceive the two pieces as one advertisement or promotional labeling piece. As noted in the guidance, when placed together, these two advertisements communicate information about a treatable disease or health condition and the name of a product approved for treatment of the disease or health condition, and effectively constitute an advertisement that communicates a product's indication for a certain medical condition without providing risk and other information. AMCP commends the FDA for considering this combination to be advertising and requiring it to include risk and other information, and the Academy supports the recommendation that such advertisement be subject to the requirements for "labeling" or "advertising."

Although AMCP strongly discourages advertising to consumers promoting the use of specific prescription drug products, the Academy is pleased that the FDA is modifying its brief summary requirements to get away from the very small print and sophisticated medical terminology currently used. AMCP congratulates the agency on allowing manufactures to use either FDA-approved patient labeling (from the Information for the Patient, Medication Guide, Patient Information, or Patient Package Insert) or highlights (including all contraindications, all warnings, the major precautions and the three to five most common adverse reactions). AMCP is pleased that the agency included the provision that any advertising disseminated in the abbreviated format include notification that the information presented is not comprehensive and provide a toll-free telephone number or web site address where consumers may obtain additional information.

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.

Sincerely,

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

Judith A. Cahill, CEBS
Executive Director