



American Pharmacists Association

Improving medication use. Advancing patient care.

February 28, 2006

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0354

Dear Sir/Madam:

Thank you for the opportunity to comment on the consumer-directed promotion of regulated medical products. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

APhA appreciates the Food and Drug Administration's (FDA) efforts to examine the regulation of direct-to-consumer (DTC) advertisements for prescription drugs, vaccines, blood products, and medical devices, as well as the effects of DTC advertisements on consumers and health care professionals. In recent years, the number of DTC advertisements in the print and broadcast media has increased significantly. With 81% of consumers reporting exposure to DTC advertisements,¹ these promotions have the potential to dramatically impact how consumers view and use prescription drugs. Because of that potential, periodic review of the regulations governing the content and format of DTC advertisements is necessary to protect patients from the potential dangers of deceptive advertisements. It is also equally important to periodically evaluate how DTC advertisements affect interactions between patients and their health care providers – including pharmacists.

The pharmacy profession supports the provision of accurate information on various health care conditions and available treatment options to consumers. DTC advertisements can serve as one useful source of this information for patients. In 1999, just two years after the Agency released new guidance for the industry on DTC advertisements, the APhA House of Delegates, the policy-making body for the Association, adopted policy supporting legislative and regulatory activities that allow DTC

¹ Food and Drug Administration. Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results. Executive Summary November 19, 2004. Page 3.

advertisements concerning health conditions treatable by prescription or non-prescription drug products (Attachment A). That support, however, is tempered with important caveats regarding the content of the information.

That same year, APhA also conducted a survey on pharmacists' views and opinions on DTC advertising. That survey found that nearly seven in ten pharmacists (67%) believe, in general, that DTC advertising provides valuable information to patients. From their responses, it is clear that DTC advertisements initiate patient inquiries concerning health issues and possible medication treatments. On average, respondents reported fielding 3.5 questions in a typical week from patients concerning drug products they had seen advertised. However, it is important to note that the survey results reflect the DTC environment six years ago – just two years after the FDA guidance was issued and DTC ads proliferated. The number of DTC advertisements the public is exposed to has increased dramatically since APhA last formally surveyed pharmacists on this topic. We can assume that the increase in consumer-directed advertisements has also led to a corresponding increase in questions to health care professionals. This conclusion is supported by the Agency's own 2002 survey which found that 43% of respondents reported that a DTC advertisement caused them to seek more information about the drug or their health, and that the most commonly reported source of this information was health care professionals. 89% reported obtaining information from their physician and 51% reported obtaining it from their pharmacist.² The survey results clearly indicate that consumer-directed promotion of prescription medications prompts consumers to ask pharmacists and physicians health and medication-related questions.

While DTC advertising may be a good mechanism to provide patients with information on health conditions and available medication treatments, as well as stimulate patient interactions with members of the health care system, they may also affect patient attitudes towards medication use. DTC advertisements can be harmful if they confuse patients, engender the impression that advertised medications are inherently safe and appropriate for casual use, or encourage the indiscriminate use of medications. The FDA has attempted to ensure that patients are not harmed by DTC advertisements by requiring advertisements to provide both the risk and benefit information for the promoted product. Although requiring the provision of risk information lessens the likelihood that patients will receive inaccurate or misleading information, the information must be presented in a balanced manner and accurately communicated to be effective.

APhA encourages the Agency to examine the provision of risk information in current DTC advertisements. As the Agency heard at the November 1st and 2nd public hearing on consumer-directed promotion of regulated medical products, numerous studies have shown that the manner in which risk information is communicated (i.e., rate of speech, visual distractions, placement within the advertisement, etc.) significantly affects how consumers process the information. It is important that DTC advertisements include risk information in a manner that is easily accessible and understandable to the average consumer.

² Food and Drug Administration. Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results. November 19, 2004. Page 3.

The Agency should also examine whether DTC advertisements contain sufficient risk information. Patients themselves have recognized the need for more risk information in DTC advertisements. 60% of respondents in the Agency's 2002 survey believed that DTC advertisements do not provide enough risk information; over half of the respondents believed that the advertisements make the products seem better than they really are; and after viewing DTC advertisements, 61% reported searching for more information about a product's possible side effects and risks.³ It appears that many consumers see a need for additional – or perhaps more accessible and understandable – risk information in DTC advertisements. Although many consumers actively seek this information after being exposed to a DTC advertisement, many others will choose not to or will rely solely on the information presented in the advertisement. If product sponsors choose to promote regulated products through DTC advertisements, they should be required to include appropriate risk information and to present such information in an accessible manner for consumers.

If a product sponsor fails to include sufficient risk information in their DTC advertising campaign or otherwise violates Agency rules or guidance, the FDA should prohibit the sponsor from running the advertisement and/or pull the advertisement if promotion of the product has already begun. APhA also recommends that the Agency institute a new requirement for product sponsors that disseminate non-compliant promotional material to consumers. Product sponsors should be required to distribute corrective information to consumers using the same means as the original advertisement. Corrective information should also be distributed to health care providers. As both APhA's and the FDA's surveys have shown, consumers frequently ask their pharmacist, physician, or other health care provider about a drug product promoted in a DTC advertisement; therefore, it is important that health care providers have accurate information about the drug products being advertised. If health care providers are not provided with corrective information, it may hinder their ability to help consumers make appropriate decisions about their health care needs. APhA strongly encourages the Agency to require DTC advertisers to provide corrective information to consumers and health care providers if their advertisements are found to be inaccurate or deceptive. In addition, we request that the Agency consider requiring product sponsors to alert pharmacists and other providers to DTC advertising campaigns *before* they are released to the public. APhA's survey found that two-thirds of pharmacists have been caught off-guard by patients asking questions about a product they were unaware the manufacturer was marketing directly to consumers. Nine in ten respondents stated that knowledge of a DTC campaign prior to its release would increase their comfort level in answering patient questions.

In conclusion, APhA supports the FDA's efforts to examine the promotion of regulated drug and medical products through DTC advertising. Periodically reviewing manufacturers' promotional activities will assist the Agency in regulating drug product promotional materials and will help ensure that patients do not receive inaccurate or misleading information. As the results of both APhA's and the Agency's surveys show, DTC advertisements are a source of drug product information for consumers and frequently prompt consumers to seek additional information about the drug product or health condition included in the advertisement. Because DTC advertisements have the potential to dramatically affect how consumers view and use medications, the FDA should regularly review DTC promotions to ensure that they present a fair balance of both benefit and risk information. Specifically, the Agency should determine if sufficient risk information is included in DTC advertisements and

³ Food and Drug Administration. Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results. November 19, 2004. Pages 3 – 5.

examine how that information is communicated to the consumer. Again, APhA also requests that the Agency consider requiring DTC sponsors to alert pharmacists and other providers before launching a DTC campaign, as well as requiring sponsors of false or misleading advertisements to distribute corrective information to both consumers and health care providers.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Director, Federal Regulatory Affairs, at 202-429-7538 or SBishop@APhAnet.org, or Susan C. Winckler, Vice President, Policy & Communications and Staff Counsel, at 202-429-7533 or SWinckler@APhAnet.org, with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Gans". The signature is fluid and cursive, with the first name "John" being the most prominent part.

John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Director, Federal Regulatory Affairs