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American Society of
Health-System Pharmacists*

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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: Docket No. 2005N-0354 -- Consumer-Directed Promotion of Regulated Medical Products; Public Hearing

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments in response to the Food and Drug Administration (FDA) September 13, 2005, *Federal Register* notice announcing the agency's meeting to hear public views on direct-to-consumer (DTC) promotion of regulated medical products. ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals and other components of health care systems. For more than 60 years, ASHP has helped pharmacists improve medication use and enhance patient safety. Our comments will address the questions the FDA asked in its announcement of this meeting,

What are additional issues that FDA should consider with respect to DTC promotion that reaches or targets specific consumer population?

Our members believe that certain advertisements, such as those for drugs for erectile dysfunction, are broadcast all day long and children are exposed to them. Parents are forced to discuss the issue, which is not the intention of the advertisement.

How can FDA help ensure that those consumers who are not medical experts understand a product's risks?

Our members have told us that the language of advertisements should be at a fourth grade level, the same that many print advertisements are written in. This will ensure that lay people understand them. Consumers have a poor understanding of the inherent risks associated with the use of any drug product; this problem is of sufficient magnitude that the FDA, in collaboration with pharmacy, medical, and industry groups, should pursue a long-term multimedia educational campaign designed to improve public understanding of the fundamental point that every medication has risks as well as benefits, and that the consumer must learn how to assess the balance of risks and benefits when deciding whether to use a medicine.

Do common advertising techniques, such as positive scenes of individuals enjoying the benefits of the advertised product during the presentation of risk information, create barriers to consumers' understanding of risk information?

ASHP believes that the discussion of risks should not be presented with positive backdrop images.

Are certain advertising strategies, such as companies offering consumers coupons, free samples, free trials, and money back guarantees for prescription drugs in both full-product as well as reminder advertisements, appropriate approaches to influence consumers?

ASHP believes that offers such as coupons, free trials and money-back guarantees should not be allowed because they convey the idea that the medication always works and that there are no risks. Such strategies also reinforce in consumers' minds that they are taking part in a commercial transaction, which undermines the reality that the prescribing of a drug is a health encounter.

The FDA also has misgivings about such offers, as evidenced by the agency's announcement in the February 6, 2006, *Federal Register* that it intends to conduct a study on how the inclusion of coupons or other price incentives in DTC advertisements may impact consumers' perceptions of the risks and benefits of the prescription drug.

How well are drug manufacturers using comparative DTC promotion?

It is uncommon for drug companies to do comparative studies. More often, they take two separate studies and compare the efficacy results, even though both drugs were not included in the respective studies. This is very misleading to consumers.

Could changes in certain required prescription drug disclosures -- the package insert for print "promotional" labeling and the brief summary for print advertisements improve the usefulness of this information for consumers?

The language in the package insert has been difficult for consumers to navigate. The new package insert regulations, issued on January 26, 2006, may prove to be helpful in this regard.

Could changes in the requirements for disclosure of certain information, i.e., the "major statement" that must convey the product's most important risk information in broadcast advertising improve the usefulness of this information for consumers?

The disclosure of this risk information is usually presented at the conclusion of the advertisement and is said quickly, not allowing consumers to fully comprehend it. ASHP recommends that this be spoken, while simultaneously appearing on the screen so that consumer can follow along.

As new communication technologies emerge, they create opportunities for novel approaches to DTC promotion. What issues should the agency consider with regard to the effect of these technologies on DTC promotion?

ASHP's members believe that the FDA needs to regulate Web-based promotions. Direct mailings to consumers -- such as CDs that are sent to consumers -- also need to be regulated.

What action should FDA take when companies disseminate violative promotional materials to consumers?

Comments solicited from our members indicate general agreement that there should be a graduated fine structure, culminating in a 6-month moratorium for a company's entire product line from DTC ads after a third offense. This would give companies pause before trying to push beyond the regulations.

Does current DTC promotion present the benefits and risks of using medical products in an accurate, nonmisleading, balanced, and understandable way?

Currently, FDA requires "fair balance" between benefits and risks, but there is no definition of "fair." This term should be defined as 50% benefit and 50% risk.

A product's risks are usually discussed toward the end of the advertisement and discussed in a rapid-fire manner. The terms often are in professional jargon and not in lay terms. Moreover, sophisticated and subtle techniques are generally used to lead the non-medical viewer, listener, or reader to subliminally minimize the significance of the risk information. This troublesome reality about the tools of marketers must be taken into account in the FDA's definition of fair balance.

New ASHP Policy on Direct-to-Consumer Advertising

ASHP has proposed new policy on DTC advertising, which has just been approved by our Board of Directors and is scheduled for ratification by our House of in June. That policy is:

To support direct-to-consumer advertising that is educational in nature about prescription drug therapies for certain medical conditions and appropriately includes pharmacists as a source of information; further,

To support direct-to-consumer advertising of specific prescription drug products, with the following requirements:

(1) That such advertising is delayed until postmarketing surveillance data are collected and assessed,

(2) That the risks and benefits of therapy are presented in a comprehensible format that allows informed decisions, and

(3) That a clear relationship between the medication and the disease state is presented; further,

To support the development of legislation or regulation that would require nonprescription drug advertising to state prominently the benefits and risks associated with product use that should be discussed with the consumer's pharmacist or physician.

Since 1997, ASHP policy has opposed consumer advertising of specific prescription medications because of the possibility that some consumers may be induced to seek inappropriate treatment as a result of such marketing. ASHP strongly believes that specific product advertising should be delayed for newly-approved products until postmarketing data can be analyzed to determine the ongoing safety of a product. Increasing demand for such products before such analysis is performed could present an unnecessary risk to the public. Moreover, our members believe that such advertising needs to be more forthright and comprehensible in regard to the disease to be treated and the risks and benefits of treatment.

ASHP appreciates this opportunity to present its comments on DTC advertising to the FDA. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at gstein@ashp.org

Sincerely,

A handwritten signature in black ink, appearing to read "Gary C. Stein". The signature is fluid and cursive, with a long horizontal stroke at the end.

Gary C. Stein, Ph.D.
Director of Federal Regulatory Affairs