

May 10, 2004

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

Re: Docket No. 2004D-0042 -- Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements

To Whom It May Concern:

The National Association of Chain Drug Stores (NACDS) is writing in response to the Food and Drug Administration's (FDA) release of the **Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements** (hereinafter "the Draft Guidance"). The Draft guidance provides suggestions to manufacturers regarding communications of risk information to consumers with print advertisements for prescription drugs.

As FDA finalizes the Draft Guidance, we ask that the agency consider the special role community pharmacies have in providing and disseminating healthcare information to consumers. We are seeking clarification of the language as it relates to in-pharmacy communications, and an exemption for retail pharmacies from these communication requirements. In our view, these are pharmacy practice issues which are in the jurisdiction of state boards of pharmacy, not the FDA.

NACDS membership consists of over 200 companies that operate 32,000 community retail pharmacies. Our industry provides more than 70 percent of the 3.1 billion prescriptions provided each year to consumers.

Overview of Pharmacy Communications

Pharmacies are one of the primary providers of prescription medication information to consumers. These educational communications help improve the use of medications, resulting in enhanced patient outcomes. Pharmacy-based activities include providing consumer medicine information (CMI) at the point of sale to patients about their prescription medications; providing information about refills to help improve a society-wide problem of adherence and persistence with medications; suggesting new and improved dosage forms and medications to patients that can help improve compliance and outcomes; and informing patients of new medications that come to market that might cost less or result in fewer side effects or drug interactions. Many of these communications are made orally, but increasingly many are also made in writing.

Thus, pharmacies are an important part of the chain of communication to consumers about health care, but FDA has overlooked these pharmacy-based communications in the Draft Guidance. Given the nature and importance of these pharmacy communications, NACDS has identified several areas of concern with the Draft Guidance that require further clarification. We agree with the agency that the information accompanying many consumer-directed prescription medicine communications is often difficult to read and of little practical use to patients.

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That is why NACDS has been an active participant in the effort to improve the quality and quantity of medication information that is provided to patients through the 1997 Keystone Action Plan, which was approved by the Secretary of HHS.

The development of this public-private sector action plan, which was mandated by P.L. 104-180, has helped to create important standards for pharmacy CMI guides, which are voluntarily provided by pharmacies to consumers with their prescriptions. The Keystone plan resulted in a suggested format for the presentation and substance of the information voluntarily provided to consumers with their prescription medications. Pharmacies are moving to help assure that the information that they provide to consumers meets these requirements.

Scope and Nature of Pharmacy Communications

The Draft Guidance does not address the unique environment within community pharmacies and the challenges for the pharmacy to disseminate the prescription drug messages. We believe that FDA should clarify that certain pharmacy communications are education or “treatment” activities, not marketing activities. Such a designation would obviate the need for pharmacies to provide the type of risk-based brief summary envisioned by the Draft Guidance. We believe that the Draft Guidance is specific for manufacturer communications that are highly promotional in nature, not educational-directed pharmacy communications.

We suggest that the specific activities described below be exempt from the accompanying information requirements as described under the Draft Guidance. Such exceptions would be consistent with those made by the patient privacy rule and accompanying guidances, mandated under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. These guidances (developed by the HHS Office of Civil Rights, OCR) specifically identify as treatment activities, not marketing activities, the following pharmacy-based communication activities:

Refill Reminders: Prescription refill reminders are treatment activities, not marketing. OCR’s December 2002 Guidance (Tab T) states that “it is not ‘marketing’ when ... a pharmacy or other health care provider mails prescription refill reminders to patients, or contracts with a mail house to do so.” That is true whether or not the pharmacy is paid by a third party (such as a drug manufacturer) to send a refill reminder.

Therapeutic Interchange: Drug substitution programs involve recommendations of “alternative treatments or therapies,” and thus should not be considered marketing. OCR wrote in its December 2002 Guidance that “alternative treatment could also include alternative medicine” and “it is not marketing when a doctor or pharmacy is paid by a pharmaceutical company to recommend an alternative medication to patients.”

Coverage and Formularies: Descriptions of the products or services covered by a health plan do not constitute marketing. For example, OCR’s July 2001 guidance stated that “informing a plan enrollee about drug formulary coverage is not marketing.” Similarly, OCR has written that describing a health plan’s prescription drug discount card program does not constitute marketing.

Counseling and DUR: HHS has written that “pharmacists’ provision of customized prescription drug information and advice about the prescription drug being dispensed is a treatment activity.” Pharmacists’ provision of information and counseling about pharmaceuticals to their patients constitute treatment, and we exclude certain communications made in the treatment context from the definition of marketing.” HHS added that “We define treatment broadly and include quality assessment and improvement activities in the definition of health care operations. Covered pharmacies may conduct such activities, as well as treatment activities appropriate to improve quality and reduce errors.”

Disease State Management and Wellness Programs: Diabetes self-management training, and similar disease state management programs, should be included within the exception for treatment. In its December 2002 Guidance OCR wrote that “disease management, health promotion, preventative care, and wellness programs” generally will not fall under the rules’ definition of marketing “because they are about the covered entity’s own health-related services.”

While manufacturers may cover the pharmacy’s costs to communicate this information to its patients, pharmacies are careful to protect their customers’ privacy and assure that the messages are consistent with the pharmacy’s own communication goals and patient care.

Clarification of Application of Drug Guidance to Pharmacy Communications

The final guidance should specify that pharmacies are not required to provide the risk information described under the Draft Guidance when they provide pharmacy educational communications to their patients. Pharmacies currently provide consumer-friendly CMI that contains valuable information that is not administratively burdensome and is easily read and understood by consumers. Given the extreme burden to pharmacies to print FDA-required accompanying information, and the marginal benefit to consumers in receiving technical information not written for them, it is not surprising that many community pharmacies find it easier and more helpful to patients to simply disseminate the CMI. As the agency reviews recommendations and proceeds with a final guidance, NACDS recommends that the agency clarify that in-pharmacy compliance and adherence messages for the drug dispensed are educational, not “promotional”, and therefore do not need the accompanying information required by the guidance.

Thank you for your attention to this matter. We would welcome the opportunity to meet with you about this issue, and to provide any further information that you may need.

Sincerely,



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