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**BY HAND DELIVERY**

Division of Dockets Management  
HFDA-305  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

RE: Docket No. 2004D-0042 -- Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions -- Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements -- Reopening of Comment Period

Catalina Health Resource (CHR) is pleased to submit further comments to the Food and Drug Administration (FDA) on the draft guidance FDA issued: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (Brief Summary Draft Guidance), 69 Fed. Reg. 6308 (Feb. 10, 2004) and 69 Fed. Reg. 30945 (June 1, 2004). FDA continues its important work of gathering information and views regarding the Brief Summary Draft Guidance and the information that must accompany direct-to-consumer (DTC) print promotions of prescription drugs. The Brief Summary Draft Guidance is an important step toward improving the quality of the information consumers receive about prescription drugs.

CHR herein elaborates further upon the comments it has already submitted to this docket on the Brief Summary Draft Guidance. CHR also reviewed the comments filed thus far with FDA and offers views on these submissions. CHR asks that FDA consider the following:

**1. Issuance of a guidance exempting in-pharmacy communications**

In its initial comment, CHR explained that the current regulatory scheme is hindering communications between pharmacies and their patients. In-pharmacy direct-to-patient (DTP) communications are an important part of the ongoing dialogue between a patient and his or her health care providers. The National Consumers League (NCL) and the National Association of Chain Drugstores (NACDS) both urged FDA to look at the special challenges of in-pharmacy communications. CHR repeats that call here and asks that FDA undertake issuance of a guidance specific to in-pharmacy DTP communications.

NACDS has asked FDA to exempt in-pharmacy DTP communications from accompanying information requirements altogether. CHR concurs with this position. DTP communications typically emphasize those things that someone who is already taking the drug should know: the

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importance of following the physician's orders, descriptions of certain side effects and adverse reactions, and how the patient can get the most from his or her prescribed treatment through adjunctive therapies, such as diet, exercise, and regularly refilling any prescriptions for chronic conditions. Where the pharmacist disseminates information about other therapeutic options, these communications occur within the pharmacist-patient relationship. All DTP communications are, in the first instance, the responsibility of the pharmacists and the State Boards of Pharmacy, not FDA.

**2. In-pharmacy compliance and adherence DTP communications are not promotional**

If the agency chooses not to exempt DTP communications, as discussed in our comment previously, CHR asks that FDA reconsider the applicability of its promotional labeling requirements to compliance and adherence communications the pharmacist distributes about the drug dispensed to the patient. As set forth in its comment, CHR believes there are compelling reasons why communications exhorting patients to comply with and adhere to the therapies their doctors have prescribed should not be regulated as promotional. Compliance and adherence communications that pharmacies disseminate to their patients are primarily educational, not promotional, even where a drug manufacturer may have sponsored some of the content.

Moreover, the patient is receiving Consumer Medicine Information (CMI) from the pharmacist with these communications. The CMI provides useful consumer medicine risk and usage information about the drug and explains how to take the medicine safely. Requiring the pharmacist to distribute additional risk information in the form of a brief summary or full professional labeling is duplicative, confusing and wasteful.

**3. Alternatives to full professional labeling or brief summary for in-pharmacy DTP communications**

Should FDA continue to require that in-pharmacy DTP communications include accompanying information, CHR asks that FDA look to the consumer-friendly alternatives already available. Numerous commentators urged FDA to extend the "adequate provision" model applicable to broadcast advertising to print promotions as well. Under this approach, print promotions, like those that are broadcast, would satisfy FDA's accompanying information requirements if the advertisement is fairly balanced, contains a major statement of the risks of the prescription drug promoted, and describes the adequate provision that has been made for the patient to receive further information.

CHR supports this reasoning and its applicability to in-pharmacy communications. Like the broadcast medium, and unlike traditional print publications, in the unique pharmacy environment it



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can become unfeasible or impractical for a pharmacist or assistant to disseminate the full professional labeling (PI) or traditional brief summary. Multiple pages of dense, technical information are not appropriate for routine dissemination to pharmacy patients and can easily be mixed up or lost in a busy pharmacy. In-pharmacy DTP promotions should be permitted to satisfy accompanying information requirements by making adequate provision for the patient to receive further information. This approach would be far more practical and useful for the pharmacy and the patient.

Alternatively, pharmacies should be permitted to satisfy accompanying information requirements by providing the CMI that accompanies the prescription drug.

#### **4. Clarification and refinement of brief summary content**

Several commentators, including the Federal Trade Commission (FTC), Pfizer, PhRMA, Wyeth Pharmaceuticals, and the University of California School of Pharmacy have urged FDA to develop data before it finalizes its brief summary reforms. Currently, FDA's Brief Summary Draft Guidance is not evidence-based. While all understand and agree that the typical brief summary is not read or used, FDA has no data regarding the alternatives.

CHR shares these concerns. FDA must test the brief summary alternatives proposed, and other formats such as the adequate provision model discussed above, to determine which formats are most useful to, and meaningful for, consumers.

CHR also believes that the final guidance must embody the "less is more" approach advocated in FDA's public statements and most recently, in FDA's *Consumer* magazine article on the Draft Brief Summary guidance. As other commentators noted, the brief summary formats FDA proposes in the draft guidance continue to be based upon translation of a document that is intended for the health care professional. Using FDA-approved patient labeling in lieu of a brief summary may also be problematic because these documents emphasize usage instructions, rather than risk information.

In the view of CHR (a view shared by other commentators), FDA should be encouraging a realistic, concise, plain language, consumer-friendly brief summary, such as an "Rx Facts" box, that emphasizes key risk information about the advertised drug. When consumers receive a brief summary, they are still many steps away from actually receiving the drug promoted. Brief summaries need not be exhaustive or even all-inclusive. Brief summaries are but one part of an educational and health care process.



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**5. Need for stronger FDA acknowledgement of compliance**

Numerous commentators have noted that the wording of the Brief Summary Draft Guidance must be strengthened from the current statements that "FDA does not intend to object" to certain types of brief summaries. Comments from AstraZeneca, Wyeth Pharmaceuticals, Merck, PhRMA, and others all emphasize that FDA must go further and state that the brief summary alternatives all fully comply with and satisfy agency requirements. If consumers are to receive better, clearer, more concise prescription drug information that is written for them, rather than the health care professional, FDA must clearly state that its brief summary alternatives are fully compliant. Without that assurance, CHR believes that drug sponsors may be reluctant to adopt a better approach to communicating with patients.

\* \* \*

CHR thanks FDA for this opportunity to comment. We look forward to working with the agency to achieve the goals of empowered consumers who are knowledgeable about their health care choices.

Sincerely,

A handwritten signature in black ink that reads "Craig H. Scott / T&amp;P".

Craig H. Scott  
President  
Catalina Health Resource

CHS/zkf