



July 25, 2005

**FILED ELECTRONICALLY**

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

RE: Dkt. No. 2005D-0169 – Draft Guidance On Useful Written Consumer Medication Information

Catalina Health Resource (CHR) is pleased to submit these comments to the Food and Drug Administration (FDA) regarding its Draft Guidance – Useful Written Consumer Medication Information (CMI) (Draft Guidance). For over ten years, CHR has been facilitating communications between patients and their pharmacists about prescription drugs. CHR offers these comments in light of its long experience assisting pharmacies in disseminating written information to patients that: educates patients about the prescription drugs that their physicians have prescribed; educates patients about complimentary adjunctive therapy; informs patients on alternative options for treatment of their health condition; and creates awareness for patients in recognizing potential undiagnosed health conditions.

CHR has long been supportive of improving the quality of information patients receive from pharmacies. CMI is an important component of the direct-to-patient, pharmacy-based communications that are vital to healthcare today. To that end, CHR offers comments on the following issues and will elaborate upon them below:

- **CMI should be used as well as useful.** CHR is concerned that the formula for Keystone-compliant CMI that FDA proposes will yield very long, complex documents that will not be useful to, or used by, patients. Indeed, the CMI Draft Guidance is at odds with other communications initiatives underway within FDA, such as revisions to the brief summary and professional labeling that emphasize a “less is more” approach and focus upon delivery of the most important – not all – information. Length is one measurement of usefulness that FDA has not included in the Draft Guidance. CHR believes in getting the right amount of information to the right patient at the right time. The objective should be twofold:
  - To stimulate a productive and meaningful conversation with the pharmacist for patients desiring a personal interaction; and
  - To facilitate the delivery of additional resource information for patients who seek and/or desire more in-depth information.

*CHR recommends that CMI focus upon concise, evidence-based information that addresses critical needs to assure that CMI is both useful and used.*

- **Coordinating the many information vehicles provided to patients will avoid redundancy and reduce overall length.** Patients are now receiving many different communications from their pharmacies, including CMI, generic or product-specific Med Guides, and FDA-approved patient labeling. Each document is at least two pages in length, and all provide overlapping risk information. Patients are not well served by redundant, lengthy documents – they will not read it, and may miss information critically important to their health.

*CHR recommends FDA look more broadly at how the agency's mandates and initiatives are increasing the volume of paper that must be delivered to patients and consider coordinating the many pharmacy-based communications to limit overall length and redundancy.*

- **Customizing CMI to meet individual patient needs is useful and beneficial for the patient.** The Draft Guidance recognizes the benefits of customizing CMI to better meet patient needs. The principle, however, is not as prominent as is warranted, for customizing a course of therapy to a patient's particular needs is one of the traditional roles of the pharmacist and physician.

*CHR recommends that the final CMI guidance provide that the pharmacy or physician may customize the CMI to a patient's individual needs, where consistent with sound pharmacy and medical practice.*

- **Public Law No. 104-180 may prohibit the CMI Draft Guidance.** Public Law No. 104-180 prohibits FDA from issuing any regulation, policy statement, or guidance that specifies uniform content or format for CMI. The Draft Guidance, however, contains numerous provisions that will have to be met for FDA to deem CMI to be Keystone-compliant that can count toward meeting the 2006 goals. While CHR supports and has long been an advocate of quality, useful information to patients, potentially, the CMI Draft Guidance violates Public Law No. 104-180.

*CHR recommends that before issuing a final guidance, FDA evaluate the extent to which such guidance complies with Public Law No. 104-180.*

## **1. About CHR**

CHR fills a unique niche in the process by which a patient becomes informed about the therapy his or her physician has prescribed. Once a patient has seen a doctor, CHR's PATIENTLink™ Newsletters become a part of the ongoing dialogue between the patient and his or her healthcare professionals about the condition the physician has diagnosed. Through its PATIENTLink™ Newsletters, CHR aids over 12,000 pharmacies in publishing communications tailored to the individual needs of nearly 100 million patients per year. The pharmacist provides a customized PATIENTLink™ Newsletter to the patient at the time he or she fills or refills a prescription. PATIENTLink™ is a folded piece of paper with content appearing on different panels of the printed page that the pharmacy staples to the bag containing the patient's prescription drug at the time of dispensing.

The first panel of PATIENTLink™ may provide the important CMI. This section of the PATIENTLink™ is intended to satisfy the "useful patient information" criteria of Pub. L. No. 104-180 and the "Action Plan for the Provision of Useful Prescription Medicine Information" drafted by stakeholders at the Keystone Center in 1996 (commonly referred to as the "Action Plan" or "Keystone Report"). CHR was one of the stakeholders who participated in the drafting of the Action Plan.

Furthering the dialogue between a patient and his or her healthcare providers, other panels of PATIENTLink™ contain additional content to assist patients in better managing their diagnosed condition and optimizing their prescribed therapy. There may be educational information about the prescribed medication or the condition the medication is intended to treat. PATIENTLink™ may contain advice about how to take the drug properly, the benefits of the drug, and the importance of refilling prescriptions for drugs that treat chronic disease. PATIENTLink™ also may include a section through which patients receive or can request information on a variety of health-related topics. In conjunction with FDA, some PATIENTLink™ Newsletters carry FDA-prepared public service announcements and health messages. PATIENTLink™ may also carry disease/therapy awareness messages and information about alternative or adjunctive prescription drug therapies. PATIENTLink™ may also discuss and promote health-related items, such as over-the-counter medications and vitamins.

The pharmacy customer receives PATIENTLink™ from his or her pharmacy in a face-to-face transaction. CHR's pharmacy and clinical staff, the sponsor's regulatory department, and the pharmacy chain's headquarters have reviewed the contents of the PATIENTLink™ Newsletter to assure that it is accurate, consistent with its sound pharmacy practices, and is contributing to the

pharmacy's communications with its patients. The PATIENTLink™ content is part of an ongoing health care dialogue between patients and their physicians and pharmacists.

PATIENTLink™ is intended to address some of the significant public health issues that arise once a patient has already been seen by his or her physician, diagnosed with a condition, and received a prescription for a course of therapy. The information is intended to support the prescribed therapy and maximize therapeutic outcomes. Moreover, FDA is increasingly looking to the pharmacy as the critical point at which patients will receive Med Guides and other important safety information about their prescribed therapies. PATIENTLink™ is an important component to broader public health initiatives to improve patients' medical outcomes.

## **2. CHR's Comments On The CMI Draft Guidance**

### **a. CMI Should Be Used As Well As Useful**

In the interest of providing "useful" written information, it appears that FDA has opted for a plain language large type version of much of the drug's full professional labeling (the "package insert" or "PI"). FDA proposes a formula for CMI that, among other things, includes all indications, all contraindications, all warnings, all precautions, all drug interactions, and the most serious and 5-9 of the most common adverse reactions. Certainly for some drugs, this information will not be extensive. For other drugs, however, translating all the risk information into patient-friendly language and required format will create a very, very long document that could easily extend for several pages as printed on a typical pharmacy printer.

It appears that the CMI Draft Guidance repeats and even exacerbates the mistakes of the traditional brief summary that FDA intended to remedy in its Draft Guidance, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (Brief Summary Draft Guidance), 69 Fed. Reg. 6308 (Feb. 10, 2004). In the Brief Summary Draft Guidance, FDA moved away from the long, dense, and illegible brief summary typically seen in prescription drug print advertising. Instead, FDA adopts a "less is more approach" and "encourages manufacturers to use clearer, less cluttered formats for presenting risk information and encourages them to focus their risk disclosures on the most important and the most common risks and to do so in language easily understood by the average consumer."<sup>1</sup>

In contrast, the CMI Draft Guidance assumes that a patient or consumer-directed document will be "useful" if and because it includes everything. The Draft Guidance does not consider

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<sup>1</sup> See <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01016.html>

whether length undermines a CMI's usefulness; for "more" may not be "better" or "useful." Nor have the benefits of this all-inclusive approach been tested. There is, to CHR's knowledge, no data demonstrating that patients would use or could use a very lengthy CMI. Indeed, such an assumption is contrary to the evidence the agency has gathered regarding the usefulness of the brief summary which shows that the typical lengthy repetition of the risk information from a drug's PI is neither useful to, nor used by, patients.<sup>2</sup>

As an alternative, CHR suggests that FDA consider permitting concise summaries of important, relevant risk information in a CMI. We support an independent third party approach to providing patients with information that allows them to understand benefit to risk descriptions. Manufacturer language is usually scientific in nature and designed to limit liability. Further, provision of concise, relevant information is the approach FDA has proposed for revisions to the PI, including creation of a "Highlights Box" of important prescribing information. *See* Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Proposed Rule (Revised Labeling Proposed Rule), 65 Fed. Reg. 81082 (Dec. 22, 2000). The CMI could include:

- All patient-relevant black box warnings.
- *A concise summary of the contraindications* describing those situations in which the drug should not be used because the risk of use clearly outweighs any possible therapeutic benefit<sup>3</sup>.
- *The clinically significant drug interactions proven dangerous to humans*<sup>4</sup>.
- Three to five of most common nonserious adverse reactions most likely to affect the patient's quality of life or compliance with drug therapy.
- *A concise summary of the most clinically significant warnings and precautions*<sup>5</sup>.

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<sup>2</sup> *See e.g.*, <http://www.fda.gov/cder/ddmac/Final%20Report/FRfinal111904.pdf>, Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs – Final Report, November 19, 2004.

<sup>3</sup> This requirement is derived from FDA's Revised Labeling Proposed Rule regarding what contraindications must be included in the Highlights Box. 65 Fed. Reg. at 81114.

<sup>4</sup> Looking to the FDA's Revised Labeling Proposed Rule, that rule would not require identification of drug interactions supported only by animal or in vitro data, unless such data were clinically relevant. 65 Fed. Reg. at 81117.

<sup>5</sup> This requirement is derived from FDA's Revised Labeling Proposed Rule regarding what warnings/precautions would have to be included in the Highlights Box. 65 Fed. Reg. at 81114.

- A statement that the information is not complete and the patient should ask the prescribing physician or pharmacist for further information.

In the view of CHR, FDA should be encouraging a realistic, concise, plain language, patient-friendly CMI that emphasizes key risk information about the prescribed drug. Other communication initiatives already underway within FDA, including the Brief Summary Draft Guidance and revisions to the PI all focus on provision of the most important – not all – information. CHR recommends FDA adopt this approach for CMI and focus upon concise, evidenced-based information that addresses critical needs to assure that CMI is both useful to and used by patients.

**b. Coordination of Information Provided To Patients Is Appropriate**

Patients are potentially receiving a great deal of information from their pharmacists: CMI, Med Guides, Patient Information Leaflets (FDA-approved patient labeling or PILs), Patient Information Sheets, compliance/adherence content provided by the pharmacy, FDA, or a third party sponsor, and information about pharmacy services, healthcare options, disease management, and therapeutic advice. If the prescribed drug's sponsor provided compliance or disease risk management information through the pharmacy, the drug's full PI might also be included. All this information will be stapled to, or otherwise crammed into the bag the patient receives from his or her pharmacists. All of these documents are communicating overlapping information. To the extent these multiple vehicles are necessitated by fine regulatory distinctions and overlapping requirements, patients are not well served by an overabundance of repetitive information. Provision of the full PI in addition to the CMI and any other mandated content is particularly troublesome – this complex document intended for the healthcare professional is not useful to the lay patient being advised how to properly take the prescribed drug.

CHR fully supports the effort underway to reach patients at the pharmacy and provide them with important information about their prescribed therapies. However, CHR urges FDA to look more broadly at how the agency's mandates and initiatives are increasing the volume of paper that must be delivered to patients. Patients may be better informed and more likely to use the important information presented to them if efforts are undertaken to limit the overall length and redundancy of the information provided to them in the pharmacy.

**c. Benefits of Customized CMI**

In the Draft Guidance, FDA recognizes that customizing a CMI to a patient's needs is useful in some circumstances. For instance, information on unapproved indications may be included in CMI "customized for individual patients." Draft Guidance, lines 185-187.

Customizing therapy to a patient's individual needs is an essential part of the traditional practice of medicine and pharmacy. The practice is not, as the Draft Guidance suggests, limited to inclusion of unapproved indications. Rather, there are many reasons why a CMI tailored to an individual patient is more useful to that patient. Most fundamentally, customized CMI is made for that patient and contains the information most relevant to his or her drug therapy – thus the customized CMI may be more concise, focused, and useful to the patient.

CHR recommends that the final CMI guidance assert the principle of customization in positive, affirmative terms. For instance, the final guidance could state:

The pharmacy or physician may customize the CMI to a patient's individual needs, when consistent with sound pharmacy and medical practice.

The CMI final guidance should recognize the importance of individualizing the information a patient receives. Providing such customized healthcare is one of the traditional roles of the pharmacist and physician. Encouraging pharmacists to customize CMI for their patients' individual medical needs and personal situations will yield CMI that is more useful to the patients that receive it.

**d. Public Law No. 104-180 May Prohibit The Draft Guidance**

CHR believes that FDA may have exceeded its authority in issuing the CMI Draft Guidance. As discussed in the Draft Guidance, on August 24, 1995, FDA proposed a regulation entitled "Prescription Drug Product Labeling: Medication Guide Requirements," 60 Fed. Reg. 44182 (Aug. 24, 1995) (Med Guide Rule). The Med Guide Rule, if it had been made final, would have set specific distribution and quality goals and time frames for distributing written information to patients about the prescription drugs dispensed to them. Congress prohibited FDA from implementing the Med Guide rule when it enacted Public Law. 104-180. The law provides that FDA:

shall have no authority to implement the proposed [Med Guide] rule ... or to develop any similar regulation, policy statement, or other guideline specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs."

Public Law No. 104-180, Sec. 601(d), 21 U.S.C. § 353 note.

The Draft Guidance, although expressed as recommendations, nevertheless specifies uniform content and format of the CMI, contravening Public Law No. 104-180. The Draft Guidance proposes "minimum appropriate characteristics of useful CMI" (Draft Guidance at line 141), that

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would have to be met for a CMI to “count” toward the 2006 goals. The Draft Guidance specifies, among other things, that a CMI will only “count” toward the Public Law’s goals if it contains:

- All of a drug’s indications;
- All of a drug’s *Warnings*;
- All of a drug’s *Contraindications*;
- All of a drug’s *Precautions*; and
- The most serious and 5-9 of the most common adverse reactions.

Moreover, the Draft Guidance contains numerous typographical and presentation requirements.

Even though the Draft Guidance is expressed in non-mandatory terms, Public Law No. 104-180 reaches and prohibits any “guideline specifying a uniform content or format for written” CMI. While CHR supports and has long been an advocate of quality, useful information to patients, potentially, the CMI Draft Guidance violates Public Law No. 104-180. CHR recommends that before issuing a final guidance, FDA evaluate the extent to which such guidance complies with Public Law No. 104-180.

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Achieving useful CMI has been a goal of CHR for many years. CHR thanks FDA for this opportunity to comment on this important initiative.

Sincerely,



Craig H. Scott  
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Catalina Health Resource