

July 25, 2005

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

**Subject: Comments on Draft Guidance on Useful Written Consumer Medication Information (CMI) [Docket No. 2005D-0169]**

Dear Sir or Madam:

On behalf of the National Association of Chain Drug Stores (NACDS) and our 200 member companies, we appreciate this opportunity to submit comments regarding the Food and Drug Administration's (FDA) draft guidance on Useful Written Consumer Medication Information (CMI).

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NACDS members operate more than 35,000 community retail pharmacies, including traditional chain pharmacies, food and pharmacy combinations, and mass merchandise pharmacies, and provide approximately 70 percent of all outpatient retail prescriptions. NACDS is strongly committed to working with FDA, consumers, and our member pharmacies to continue to make strides in improving the quality of written prescription information received by consumers.

**I. Overview.**

NACDS agrees with FDA that the private sector action plan developed in 1997 ("Keystone plan") is "the culmination of a long history of efforts aimed at ensuring that consumers receive useful information regarding their prescription medications." Since 1995, we have cooperated with FDA in its efforts to develop appropriate standards for CMI, including participation in the 1996 Keystone steering committee and the agency's subsequent public meetings, collaboration with the National Council on Patient Information and Education (NCPPIE), submission of formal comments, and continuous, informal discussions with agency managers. We share a common goal with FDA and other stakeholders of providing 95 percent of consumers receiving new prescriptions by 2006 with useful CMI, as originally proposed by FDA in its 1995 proposed rule and as codified in Public Law 104-180.

We believe that the Keystone plan has already led to important improvements in the quality and quantity of written information provided to consumers regarding their medications. As the 2001 national evaluation study commissioned by FDA found, the percentage of consumers receiving written information from pharmacies increased over the last 10 years from 32 percent to the current level of 89 percent. Most importantly, the Keystone Plan provides FDA and private stakeholders with specific criteria (“Keystone criteria”) that have been applied to improve the quality of CMI and to ensure that it is:

- scientifically accurate;
- unbiased in content and tone;
- sufficiently specific and comprehensive;
- presented in an understandable and legible format that is readily comprehensible to consumers;
- timely and up-to-date; and
- useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm.

We recognize that FDA intends the draft guidance to be a useful means to supplement the Keystone criteria for key stakeholders, and that FDA includes pharmacies among its principal intended audiences. However, NACDS is concerned that the issuance and application in 2005 of a draft guidance that departs meaningfully from the Keystone criteria would render it impossible for FDA’s collaborating stakeholders to achieve the legislatively mandated target in 2006. Our overriding concern is that application of the draft guidance would lead to lengthier but less useful CMI that patients will not read and pharmacies will be unable to provide through their existing computer systems. The results would make it more challenging to achieve the 2006 target and could result in the renewed possibility that FDA would attempt to impose mandatory requirements ill-suited to improving CMI quality and access.

## **II. Draft Guidance Would Result In Lengthier But Less Useful CMI.**

Written prescription information must be balanced to provide important risk and benefit information. The purpose of useful CMI is both to encourage the patient to take the medication, and to enable the patient to take it safely and appropriately. NACDS is concerned that the draft guidance indicates that CMI cannot be scientifically accurate, unbiased, specific or comprehensive without inclusion of every indication, contradiction, warning, precaution, and most serious or frequent adverse reactions, for a given prescription drug. According to FDA, it would not deem CMI to be useful under the 2006 target if it lacks any of this information. We are concerned that the contents of such medication guides would convey too much risk information, and not enough benefits of the drug, potentially decreasing compliance with medications.

The draft guidance would also require use of specific design features, type sizes, colors, spacing, lettering and fonts. NACDS is concerned that application of the draft guidance would render CMI less effective and user-friendly, consequently leaving consumers less informed about their medications.

There are more than 80 different types of pharmacy computer systems in use today, some that are “homegrown.” Not all these computer systems can support the type of format and layout described in this draft guidance. Unless the agency or some other third party is able to help fund a total replacement of or provide a significant upgrade of these pharmacy-based computer systems, it is not likely that many pharmacies will be able to have the technological capabilities to print the desired quantity of information in the format specified here.

Whether intentionally or not, the draft guidance would require stakeholders to develop CMI with content analogous to the “brief summary” of risk information required in prescription drug advertisements. Under 21 C.F.R. § 202.1(e), FDA requires that a prescription drug advertisement contain a “true statement of information in brief summary relating to side effects, contraindications... and effectiveness,” including “each specific side effect and contraindication... contained in required, approved, or permitted labeling for the advertised drug dosage form(s)”. In short, the regulations specify disclosure of all the risk information in a drug product’s approved labeling, and print advertisements will typically reprint all of the risk-related sections of a drug product’s labeling.

The agency has acknowledged repeatedly that the brief summary requirement does not effectively inform consumers or providers. It would follow that a comparable CMI requirement would similarly fail to effectively inform them. A 1999 FDA survey of individuals who saw a consumer-directed prescription drug print advertisement found that 56 percent read the brief summary “not at all” or “a little”; a 2002 follow-up study found that percentage rose to 73 percent. As FDA recently stated:

“Typically, manufacturers fulfill the brief summary requirement by including the complete risk related sections of the FDA-approved professional labeling in the ad verbatim, in small type. Risk information presented in this manner is designed to satisfy applicable regulations but is not user friendly. While this risk information is technically in compliance in that it contains important information on benefits and risks, it does not convey key information effectively to many consumers.”

NACDS encourages FDA to revise the CMI draft guidance to reflect the acknowledged liabilities of the wholesale reproduction of risk-related sections of a drug product’s labeling in CMI. The draft guidance should reflect the approach advocated in FDA’s 2004 draft guidance on consumer-directed print advertisements; namely, to encourage the “use [of] clearer, less cluttered formats for presenting risk information and... to focus... risk disclosures on the most important and the most common risks and to do so in language easily understood by the average consumer.” We believe that information presented to consumers must not only be useful, but also must also encourage patients to actually read it and improve their compliance. Patients may simply not read information that is two or even three pages long; clearly, this is not a desired outcome. More than 80 percent of the CMI currently produced is already greater than two pages in length, with the average length being one and a half pages. Providing too much information, and too much risk information, runs the risks of both rendering CMI less useful and of discouraging medication compliance.

### **III. Application of the Draft Guidance Would Impede Availability of Currently Available, Useful CMI.**

As discussed above, much of the CMI that is currently compliant with the Keystone criteria would likely be determined by FDA to be “not useful” for purposes of the 2006 target if the agency were to use the draft guidance as its basis for evaluation. Because the draft guidance would effectively supersede the Keystone criteria to redefine “useful” CMI, private stakeholders, including drug manufacturers, wholesalers and distributors, physicians and pharmacists, consumer organizations, and drug information database companies, would be compelled to revise or abandon CMI that meets the Keystone criteria but does not satisfy the draft guidance.

The draft guidance raises important doubts concerning current CMI that may be Keystone compliant yet not satisfy the draft guidance’s requirements, which require further clarification. For example, in describing how CMI should encourage consumers to talk with “healthcare professionals”, the draft guidance omits any reference to pharmacists. Instead, it states that compliant CMI can simply state: “If you would like more information, talk with your doctor.”

NACDS is also concerned about the practical ability for the marketplace to reach a goal of 95 percent of patient receiving CMI. Although absolutely laudable, just the fact that more than 5 percent of the population speaks English as a second language, or may have difficult reading or comprehending information that is provided to them, adds to the challenges in being able to meet the 95 percent goal. It is estimated that over 90 million Americans have difficulty understanding and using health information; 80 million Americans have potentially blinding eye diseases; 14 million Americans are estimated to have low vision, over 30 million Americans are learning English as a second language and 4.4 million households encompassing 11.9 million Americans are “linguistically isolated”.

We believe that distribution of CMI should be limited to new prescriptions, with the option for the patient to ask for another copy of the CMI when obtaining a refill prescription. Moreover, any assessment of the quality and quantity of written information provided must also include all dispensing sites, including mail order facilities, hospital outpatient departments, Federally-funded health care facilities (i.e. PHS clinics, VA and DOD hospitals), physician dispensers, and other places where prescription drugs are dispensed on an outpatient basis.

NACDS is consequently concerned that application of the draft guidance would effectively and unintentionally undercut FDA’s long-term policy of “cooperation with health professionals and others in both the public and private sectors and reliance upon expanding privately sponsored initiatives in patient education... to provide patients with needed information about prescription drugs.” (47 Fed. Reg. 39147 (1982)).

It should be noted that the timing of the draft guidance may also serve to hinder public-private cooperation to meet the 2006 target. As a result of the draft guidance’s late issuance in mid-2005, it is highly unlikely that private stakeholders would be able to apply the draft guidance in time to conform existing CMI to its very specific recommendations before the 2006 deadline.

The draft guidance would potentially have had a more beneficial effect had it been issued in a more timely manner following FDA's July 2003 public meeting on the status of useful written prescription drug information for consumers. This guidance is being issued two years after that public meeting, and after database companies have been revising their CMI to conform to the Keystone Criteria. We encourage the agency to reconsider whether, at this late date, the draft guidance will serve its intended purpose of facilitating the compliance of CMI with the Keystone criteria by 2006. Given the limited time available, since stakeholders have employed the actual Keystone criteria for several years to revise and evaluate CMI, the agency should apply the actual criteria rather than the draft guidance to determine whether CMI is "useful" for purposes of the 2006 target.

**IV. Application of the Draft Guidance May Result In Imposition of An Infeasible, Mandatory CMI Regime.**

Should application of the draft guidance compel private stakeholders to withdraw Keystone-compliant CMI from circulation in order to revise it to be compliant with the draft guidance, it would be significantly more challenging for FDA and private stakeholders to meet the 2006 goal. Under Public Law 104-180, FDA would likely "seek public comment on other initiatives" to achieve the 2006 goal, including mandatory CMI requirements similar to those in its 1995 proposed rule on Medication Guides ("MedGuide").

NACDS is concerned that a mandatory CMI, or MedGuide, regime resulting from application of the draft guidance would fail to improve the quality and availability of CMI. It is highly unlikely that a MedGuide mandate could compel private stakeholders to accomplish more than what they and FDA have achieved through voluntary efforts. Nor is it clear how the agency could or would wish to undertake such a substantial new mandatory program with its limited resources and competing public health responsibilities. A mandatory MedGuide program would also threaten to eliminate numerous commercial CMI products, undercut drug information database companies in the marketplace, and sidetrack the gradual but substantial progress that has already been made through voluntary public-private efforts.

Under its MedGuide regulation at 21 C.F.R. § 208.24(b), FDA requires manufacturers of prescription drugs "for which a Medication Guide is required..." to be "responsible for ensuring that Medication Guides are available for distribution to patients by either:

"(1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or

"(2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product."

The planning and preparations necessary to assure the success of such a mandatory regime for all prescription drug products have simply not taken place. For example, if FDA sought to mandate the availability of electronic MedGuides for prescription drug products, there has been no consideration of whether specific CMI formats or content are technically compatible with the processing or printing capabilities of the pharmacy database software products marketed by dozens of vendors or the diverse electronic retail computer systems for pharmacy records, prescription and label processing, adverse drug reaction (ADE) screens, and online claim adjudication utilized nationwide.

If it is infeasible to require the electronic distribution of mandatory MedGuides, implementation costs would be greatly exacerbated if manufacturers or third party vendors were compelled to produce and distribute pre-printed pads of hard-copy, product-specific MedGuides to pharmacies and other dispensers nationwide, who in turn would be compelled to match specific pieces of pre-printed, mandatory MedGuides with each filled prescription. While FDA has clearly stated that its MedGuide regulation “places the ultimate responsibility for ensuring the content and availability of patient information with the manufacturer of the drug product,” (63 Fed. Reg. at 66394) the FDA has not resolved how it would assure manufacturers could guarantee the timely delivery of sufficient numbers of up-to-date and appropriately formatted MedGuides for all prescription drug products available at community pharmacies nationwide or through mail-order. Absent adequate planning and resolution of these and other technical obstacles, a mandatory MedGuide regime would not appear to be feasible at present, and would inevitably increase prescription drug and transaction costs that would ultimately be borne by consumers.

NACDS also believes that the agency should continue to work with pharmacy providers to create a single “medication guide” for prescription medications that require a mandatory medication guide. For example, two major categories of prescription drugs – antidepressants and Cox-2/NASIDs - are now required to be dispensed with an FDA approved medication guide. For the antidepressants, the FDA has allowed manufacturers to use a uniform medication guide for these drugs to communicate new risk warnings, and manufacturers have formed a consortium to help distribute these guides (in pads of paper), through a single distribution system. We appreciate that the agency and the manufacturers have worked together to decrease the burden on pharmacists regarding the distribution of this important information. However, there are more technologically-efficient ways to distribute this information.

We have met with the FDA already about allowing pharmacies to provide these mandatory medication guides electronically, rather than use a paper-based pad program. We believe that the risk information required to be provided by pharmacists in this medication guide should be incorporated into the written information (i.e., CMI) that the pharmacist is already providing to the patient, rather than requiring that a separate sheet of paper be provided. This type of approach will make it more likely that the pharmacist will provide the information to the patient, as well as more likely that the patient will read the information.

## V. Conclusion

With less than six months until 2006, and given stakeholders' historic reliance upon the actual Keystone criteria to improve CMI nationwide, NACDS recommends that FDA substantially revise or withdraw the draft guidance and apply the actual Keystone criteria in determining whether CMI is "useful" for purposes of the 2006 target. We applaud the efforts of the database companies that have been working to revise their products toward the 2006 goal so that pharmacies have the ability to distribute to patients information that is consistent with the Keystone criteria.

Should FDA decide to move forward with this guidance, they should assure stakeholders have adequate opportunity to understand and apply the revised guidance, which in turn would require delaying the timing of its evaluation until at least 2010. We recommend that such an evaluation might occur consistent with the Healthy People 2010. That is, FDA could use the Keystone Criteria for the 2006 assessment, and use a significantly-modified final draft guidance for the 2010 assessment.

However, the economic impact to pharmacies, other dispensers (including Federal government agencies), database companies, and others to revise and distribute information that would have to meet the draft CMI criteria should be studied and assessed by FDA. That is because the database companies have been working hard to meet the Keystone criteria, and would now have to contend with a new guidance document. Many pharmacies have also been preparing their prescription systems to print CMI that meets the Keystone Criteria, but not necessarily the type of information that would have to be printed in order to meet the draft guidance criteria. We question whether the additional information that FDA would require be provided in CMI through this draft guidance would actually be "useful" to patients.

NACDS appreciates the opportunity to provide comments on this Draft Guidance. Please call on us if we can provide any additional information or clarify any of the issues raised in this letter.

Sincerely,



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