

July 8, 2002

Ms. Kimberly Littleton Topper  
Center for Drug Evaluation and Research  
Food and Drug Administration, HFD-21  
5600 Fishers Lane  
Rockville, MD 20857

**RE: Drug Safety and Risk Management Advisory Committee, July 17, 2002**

Dear Ms. Topper:

On behalf of the National Council on Patient Information and Education (NCPIE), this letter is in response to your request for comments on ways to improve the usefulness of consumer medication information (CMI) distributed with prescriptions filled at pharmacies. We would appreciate the opportunity to present our comments orally at the FDA Drug Safety and Risk Management Advisory Committee scheduled for July 17, 2002 at the Holiday Inn, Gaithersburg, MD. As defined in the agenda for this meeting, our comments will help identify and define “scientific methods to assess and monitor whether effective communication of key information to patients is occurring.” However, the following comments do not necessarily represent the opinion of all members of our coalition.

NCPIE is a non-profit coalition of over 135 members committed to improving health professional/patient communication about the appropriate use of medicines. As such, NCPIE served on the Keystone Committee (along with many of our coalition members) in 1996 to develop the *Action Plan for the Provision of Useful Prescription Medicine Information*.

**Historical Perspective: Public Policy Initiatives to Improve CMI**

A brief review of initiatives to improve consumer medication information is important to appreciate the historical perspective in which the Drug Safety and Risk Management Advisory Committee will make its recommendations.

- The Omnibus Budget Reconciliation Act of 1990 (“OBRA ‘90”) mandated that pharmacists extend an offer to counsel Medicaid recipients about their prescription medicines. Subsequent to implementation of this federal provision in 1992, 45 states amended their pharmacy practice acts to extend the offer-to-counsel to non-Medicaid customers as well.

- *Healthy People 2000* and *Healthy People 2010*, objectives under “Food and Drug Safety” (2000) and “Medical Product Safety” (2010) address prescriber and pharmacist counseling; communication about medicines’ appropriate use and potential risks; and quality of written medicine information. See <http://www.health.gov/healthypeople>.
- *Action Plan for the Provision of Useful Prescription Medicine Information*, developed by the Keystone Committee (including NCPIE) in 1996, and accepted by HHS Secretary Donna Shalala in 1997. The *Action Plan* reiterated the critical role that healthcare professional-patient communication and counseling play in promoting appropriate and safe medicine use.
- Expansion of direct-to-consumer pharmaceutical advertising following the FDA’s relaxing of broadcast DTC guidelines in August 1997.
- Implementation of FDA-approved “Medication Guides” for a limited number of “high risk” medicines.
- “National Consumer Medicine Safety and Education Program,” proposed by NCPIE in 1997 at FDA public meetings about the FDA Modernization Act of 1997. This program would: (1) educate consumers and health care providers about improvements in CMI; (2) promote question-asking and information-sharing to improve medicine communication, knowledge, and usefulness; and (3) help consumers and caregivers recognize and report medication-related errors.
- *To Err is Human*, released by the Institute of Medicine (Nov. 1999), focused national attention on the magnitude/impact of medication errors, especially in hospitals.
- NCPIE national public awareness campaigns, such as: “Talk About Prescriptions” Month (observed every October since 1986), *Alcohol and Medicines: Ask Before You Mix* (1993), the National *Brown Bag* Medicine Review Program (initiated 1992), and “Be MedWise” (2002), continue to stimulate and reinforce the need for quality medicine communication between consumers and healthcare providers.

### **Significance of this Public Policy Foundation**

The consensus among medicine information stakeholders is that CMI is most effective when it involves written information supplemented by oral counseling. For two decades, various state, federal, and voluntary initiatives have supported this two-pronged approach, as outlined above. The July 17, 2002 hearing may focus primarily on improving written CMI. However, it is only with the full commitment of all health care professionals to actually “Talk About Prescriptions” (as NCPIE calls its national observance each Oct.) that patients will understand the possible risks, use their medicines safely, and realize their medicines’ full benefits through enhanced CMI.

### **Outlining a Research Agenda to Improve CMI**

Over the years, NCPIC has served as a catalyst by identifying areas for future medicine communication research. Specifically, please refer to our April 27, 2000 letter to FDA about research in the next phase of evaluation of written medicine leaflets. Today, we recommend a CMI research agenda that includes the following issues:

1. How much information is too much? For those prescription medicines that require Medication Guides, do we know their effect on patient understanding of possible risks? Do we know the extent to which the Medication Guides contribute to appropriate use? Do we know how Medication Guides have affected patient adherence and health outcomes?
2. What effect does a simplified format for CMI have on safe medicine practices? For example, what post-marketing research is being done on the new “Drug Facts” label now required on most non-prescription medicines?
3. Focusing, for example, on the five or six prescription medicines most commonly used by persons aged 65 and older (in order, Prilosec, Norvasc, K-Dur 20, Lanoxin, Lipitor, and Celebrex, per <http://www.familiesusa.org>, June 24, 2002), research could be conducted to examine: (a) different formats for, and quantity of information conveyed on, pharmacy-distributed leaflets; (b) different types of follow-up contact (from physicians, pharmacists, nurses, physician assistants, etc.) within various time frames of starting a new prescription; (c) medicines that are selected for extensive DTC campaigns vs. those that are not: does the supplemental manufacturer-provided information that may reach patients for whom these medicines are prescribed have any effect on their adherence, understanding of risks vs. benefits, and/or safe medicine use?
4. Advice to “use one pharmacy for all of your medicines, and complete the patient profile form” are common, non-controversial suggestions to promote safe medicine use. What percent of patients aged 65 and older have such forms on file at their local pharmacy? Are these patients asked each time they come in for a new prescription to fill out and/or update their form? Are patients routinely asked about non-prescription medicines and dietary supplements they may be using, so that this information can be added to their profile?
5. Much attention has been focused on adoption of computerized physician-order entry systems, primarily in hospitals, as one way to reduce medication errors. While the advent of “PDA” technology (e.g., Palms) has made this an option for ambulatory settings as well, implementation to date is extremely limited. In 2000, Susanna Bedell, M.D., cited discrepancies of up to 75% in reported versus recorded medications (<http://archinte.ama-assn.org/issues/v160n14/abs/loi90676.html>). Bedell’s research was conducted in physicians’ offices. What if community pharmacies sent a copy of a “high-risk” patient’s profile form to each of their prescribing physicians?

Page 4 of 4  
July 8, 2002

5. (continued) To what degree could such technologically-enhanced pharmacist-prescriber communication improve CMI overall?

NCPIE remains committed to ensuring that consumers receive useful information about their prescription medicines. We forward to working with FDA and other committed stakeholders to improve the quality of both oral and written consumer medicine information. I look forward to presenting these comments personally on July 17. Please contact me at (301) 656-8565, ext. 12, should you have any questions.

Sincerely,

Wm. Ray Bullman, M.A.M.  
Executive Vice President  
E-mail: [wrbullman@erols.com](mailto:wrbullman@erols.com)  
<http://www.talkaboutrx.org>  
<http://www.bemedwise.org>

cc: Linda Golodner, NCPIE Chair and President, National Consumers League