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April 27, 2000

DOCKET # 00N-0352

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

Dear Sir/Madam:

I am pleased to submit comments on the "Status of Useful Written Prescription Drug Information for Patients" (*Federal Register*, Vol. 65, No. 29, Feb. 11, 2000, pp. 7022-2023). The following comments do not necessarily reflect those of our entire membership.

The National Council on Patient Information (NCPIE) is a coalition of over 150 organizations committed to improving communication between health care professionals and patients to ensure appropriate medicine use. 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 (Action Plan)*.

NCPIE also participated in the FDA's Feb. 29-March 1, 2000 workshop to discuss the preliminary eight-state evaluation of written patient leaflets distributed in 300 community pharmacies. First, we would like to echo principal researcher Bonnie Svarstad, Ph.D. (Univ. of Wisconsin), who noted the "remarkable progress" that has been made with over three-fourths of patients receiving written medicine information. According to FDA's own national consumer surveys, this represents a five-fold increase since NCPIE's formation in 1982.

The following comments will specifically address two questions (per *Fed. Reg.*): *Should the evaluation panel include consumers with varying educational backgrounds, and if so, how should they be involved in the evaluation process?* and, *What should the minimum standard or threshold that must be met for written information to be considered useful?*

The FDA asks if the evaluation panel should include "consumers with varying educational backgrounds." NCPIE believes the answer is yes. However, the panel should also include practicing health care professionals, not just academics.

00N-0352

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As the end-user of written patient leaflets, consumers may have a very different perspective of “usefulness” compared to that of academics who comprised the original panel. For example, the original panel may have assumed the “best case” scenario where the written information was preceded by oral counseling in the physician’s office, and delivered with oral counseling at the pharmacy.

In terms of how to involve consumers, perhaps the FDA could look to other federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ). When we developed with AHRQ (then AHCPR) the brochure, *Prescription Medicines and You: A Consumer Guide* (which has been translated into five languages), focus groups of diverse Baltimore-area consumers were invited to review early drafts. Their input proved invaluable. Further, the Health Care Financing Administration has a National Medicare Education Program (on which NCPIE serves) from which consumers could also be selected for an evaluation panel. The Administration on Aging (AoA) could also be tapped to identify consumer-evaluators. (In the mid-1990s, NCPIE and AoA worked together to develop the first national medicine education check-up program.) Provided adequate funding were allocated specifically to focus group selection and management, NCPIE could serve as the convener/ facilitator.

In terms of capturing mail order, on-line, and “other non-retail pharmacies” for sampling, the FDA could work with the Pharmaceutical Care Management Association (which serves on NCPIE’s Board) to survey mail-order pharmacies as to their vendor source for patient leaflets. We believe that PCMA would be most cooperative in this venture. For on-line pharmacies, the top five that have earned the “VIPPS” seal for quality all provide on-line patient information, which is easily accessible to site visitors regardless if a purchase is made. Samples from other online vendors (e.g., Multum, Clinical Reference Systems) can also easily be obtained via the Internet.

I also urge FDA not to be overly strict in establishing the threshold or minimum standard that must be met for written information to be considered useful. It is unrealistic and unlikely that any written information will conform to 100 percent of the 10 criteria being used (some of which are quite subjective). Dr. Svarstad’s assessment reports that over 75% of items received high ratings on five criteria (drug and benefits, adverse reactions, unbiased in content and tone, legible and comprehensible, accurate and disclaimer). Other criteria (directions, contraindications, precautions, storage and general information, and publication information) received lower ratings and indicate that improvement is needed in these areas. Incremental improvements, particularly in conveyance of risk information, should be considered as additional progress.

Additionally, given the fact (stated repeatedly at the 2/29-3/1 workshop) that pharmacists often “edit” patient information produced and provided by third-party vendors, patient information in full (100%) compliance with the Action Plan criteria may never reach consumers through the retail pharmacy. This information “disconnect” (vendor/pharmacist/consumer) is a health professional practice issue that must be addressed through awareness and education.

As befits our mission of ensuring appropriate medicine use through improved communication, we support continuous evaluation and improvement of written patient medicine leaflets. Yet we believe that some omissions in the preliminary evaluation (reportedly due to funding constraints, Svarstad told the workshop attendees) should be addressed in the next phase of this project:

- Assessment of extent to which the printed information was mediated by the pharmacist: was it conveyed statically, without any offer-to-counsel; or with actual counseling by pharmacists?
- Variability in content (or potential content) of leaflets delivered to patients due to editing by pharmacists;
- Among top 10 brand-name prescription medicines by number of prescriptions written (see list, *Drug Topics*, March 6, 2000, p. 69), for those that are the focus of direct-to-consumer advertising campaigns, assessment of the (printed) patient information against the *Action Plan* criteria – many patients or would-be patients are referring to these materials in tandem with the pharmacy-distributed leaflets, and their usefulness should be assessed as well;
- Evaluation of the leaflets' influence on patient compliance two weeks following the start of a new prescription medicine: if the leaflets do not influence in a positive way patients' compliance and health outcome, then we should re-direct our valuable research dollars towards other medicine communication issues.

Results of the next round of leaflet evaluation deserve the similar stature and resource commitment as the March 11, 1999 White House launch of a national public information campaign to help consumers learn more about nonprescription medicines and the new "OTC" labels. Given President Clinton's accelerating policy push for a Medicare outpatient prescription drug benefit (witness his April 26, 2000 press conference), it behooves all medicine information stakeholders to take advantage of heightened public interest – especially among older adults – of medicine issues generally.

For example, in August 1998, NCPPIE proposed to FDA establishment of a collaborative, national Consumer Medicine Safety and Education campaign, the goals of which would be to:

- Educate consumers and health providers about changes and improvements in medicine information;
- Promote question-asking and information sharing as valuable tools to improve communication, knowledge and usefulness; and
- Better equip consumers and caregivers to recognize and report medication-related errors.

Page 4 / April 27, 2000
DOCKET # 00N-0352

Such a campaign could develop, disseminate, and evaluate a single medication-safety /education slogan and several standard educational messages tested for maximum consumer understanding. It could utilize multiple information channels - the mass media, public service announcements, the Internet, and point-of-purchase materials.

Now is the time for FDA to commit developmental support and on-going resources for this effort. NCPIE, as convener and catalyst, can garner support for the campaign among groups representing health care providers, consumers, and the pharmaceutical industry. Initial campaign messages could be disseminated by Oct. 2001 to coincide with the 16th national "Talk About Prescriptions" Month, which could be reformulated as "National Medicine Safety and Education Month." Such an educational program was recommended in the *Action Plan for the Provision of Useful Prescription Medicine Information*.

Voluntary, private sector efforts to improve the distribution and quality of patient medicine information are succeeding -- and attracting worldwide attention. In fact, this year NCPIE has been invited to present on U.S. voluntary efforts at three international conferences (two in London, one in Finland). By raising the bar too high, FDA's year 2000 assessment will impede momentum and progress by the private sector. By recognizing progress (while acknowledging areas of weakness), and working with key stakeholders like NCPIE and major drug information vendors, progress towards the 2006 final goal will continue.

NCPIE remains committed to ensuring that consumers receive useful information about their prescription medicines, and looks forward to working with you to improve the usefulness of all medicine information, both oral and written.

Sincerely,



Wm. Ray Bullman, M.A.M.
Executive Vice President



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