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**Wm. Ray Bullman, Executive Director,
National Council on Patient Information and Education (NCPIE)**

**FDA/CDER Public Meeting
Monday, August 17, 1998
Washington, DC**

5471

TOPIC: *How can CDER assure that health care professionals and consumers get the information they need about drugs? What methods of communication would be most effective in getting additional information about drugs to health care professionals and consumers?*

Comments: Thank you for providing me the opportunity to participate in today's meeting, and on this panel. The National Council on Patient Information and Education (NCPIE), of which the Food and Drug Administration (FDA) is a founding member, is pleased that the Center for Drug Evaluation and Research (CDER) is seeking input into how it can help assure that health care professionals and consumers get the information they need about medicines. This objective is similar to NCPIE's mission, which is to stimulate and improve communication of information on the appropriate use of medicines to consumers and health care professionals.

NCPIE, as a participant in the development of the 1997 "Action Plan for the Provision of Useful Prescription Medicine Information," is concerned about the quantity and quality (usefulness) of information being conveyed:

- as part of DTC ads,
- at the point of prescribing and dispensing; and
- with supplemental medicine information provided to patients along with their prescription medicines.

In our comments to FDA last October, on the topic, "Draft Guidelines for Industry: Consumer- Directed Broadcast Advertisements," we urged manufacturers to experiment with different formats for supplemental written information as described in the "guidelines" section (Chapter 3) of the "Action Plan."

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In light of CDER's recent addition of down-loadable, drug-specific information leaflets for consumers on its web site last week, today I would repeat several suggestions I made to the agency last Fall.

First, CDER is encouraged to commission research to determine which formats of supplemental written information are most useful in terms of:

- (a) improving consumers' medicine adherence and health outcomes as determined by a health care professional, and
- (b) improving information exchange between the patient, his/her prescriber(s), pharmacist, and other health care professionals.

The study could concentrate on a prescription drug or class of drugs representing the top drug or drugs used predominantly by women, older adults or children, and that has been targeted for heavy DTC broadcast or print advertising since the agency relaxed the guidelines in August 1997. Findings from this research can provide guidance to those engaged in developing their own versions of "useful" written information. Although the 1997 "Action Plan" recommends specific criteria for the content and format of useful written information, the recommendations are untested in the real world.

Second, CDER is encouraged to support the development of a collaborative, national Consumer Medicine Safety and Education Program. The goals of the program would be to:

- educate consumers and health providers about changes and improvements in prescription 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.

National Consumer Medicine Safety and Education Program

The campaign can be modeled after the Partnership for Food Safety Education, which includes industry, consumer groups, HHS and several other federal agencies, including CDC, USDA, and the Department of Education.

The Partnership is developing, disseminating, and evaluating a single food-safety slogan and several standard educational messages. The partnership is currently funded by nine industry organizations. FDA and USDA will expend \$4 million of 1998 funds to support this and other education activities. The Partnership enlists a national network of public health, nutrition, food science, education, and special constituency groups to support the campaign and extend its reach.

The Partnership has launched a nationwide food-safety education campaign targeting the general public with a focus on key concepts tested for maximum consumer understanding. The "FIGHT BAC" campaign includes a slogan, logo, and identifiable character. The campaign utilizes multiple information channels - the mass media, public service announcements, the internet, point-of-purchase materials, and school and community outreach efforts - to alert consumers about the problem of food-borne illness and to motivate them to take action. It promotes September as National Food Safety Month.

Recommendation

CDER is urged to take the lead, among federal agencies, in developing a memorandum of understanding to organize and support a national Consumer Medicine Safety and Education Program modeled after the Partnership for Food Safety Education. NCPIE is willing to take the lead, among the private sector stakeholders, to garner support for the program among groups representing health care providers, consumers, and the pharmaceutical industry.

In the ideal, initial campaign messages could be disseminated by October 1999 to coincide with the 14th 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." Consumer organizations, FDA, industry groups, and other stakeholders should all participate by contributing resources towards collaborative message design, testing, and implementation.

Why Americans Need Such a Campaign

Patients die, fail to recover or their conditions worsen due to improper medicine use. Estimates of medication noncompliance are well over 50% for certain drugs or drug classes. Poor compliance among chronic disease sufferers can result in uncontrolled disease, and progression of disease.

For example, increased risk of death after myocardial infarction has been observed in patients with poor compliance to beta-blockers. Noncompliance with infectious disease therapy (tuberculosis for example) can result in treatment failure, and transmission of the infection. Consumers also place themselves and others at risk due to the effects of avoidable side effects and adverse reactions. Among the elderly, an estimated 32,000 people suffer hip fractures due to falls.

The Department of Transportation notes that over 100,000 automobile crashes -- resulting in over 1,500 deaths -- are linked to driver drowsiness due to, among other things, the sedating effects of medicines to control blood pressure, treat various psychological disorders, or, in the case of some OTC, to treat allergy symptoms.

Recently, the National Highway Traffic Safety Administration initiated the "Drug Evaluation and Classification Program" in 27 states. Specially trained officers, called Drug Recognition Experts (DREs) are empowered to evaluate drivers for the influence of LEGAL MEDICATIONS that might interfere with driving ability.

Maryland's DRE coordinator, First Sergeant Bill Tower, was quoted in May 1998 as saying, "the drug-impaired suspect has escaped detection and prosecution far too often. That has now changed."

Clearly, no one wants loved ones driving while impaired with alcohol or illicit drugs. Nor do we want the public placed at risk from sedated drivers.

But I prefer that my parents know the risks of their medicines, and that they know they can check with their doctor or pharmacist about side effects when they receive a prescription or are selecting an OTC, so they won't put themselves and others at risk by getting behind the wheel. That's the importance of education.

Finally, in 1997, national pharmacy organizations convened a symposium to develop strategies for overcoming barriers to effective oral counseling about prescription medicines. Lack of consumer awareness of:

- (1) the value of medicines properly used; and
- (2) the potential for harm from medicines used incorrectly was identified as a major barrier at the symposium. A recommendation from the symposium is development of a sustained, national consumer education campaign.

NCPIE is committed to ensuring that consumers receive useful information about their prescription medicines, and to participating in the design, development, and implementation of such a national consumer medicine safety and education program.