NATIONAL CONSUMERS LEAGUE

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January 6, 2006

BY ELECTRONIC MAIL

http://www.fda.gov/dockets/ecomments
Division of Dockets Management (HFA –305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

COMMENTS OF THE NATIONAL CONSUMERS LEAGUE TO
DKT. No. 2005N-0394
COMMUNICATION OF DRUG SAFETY INFORMATION

The National Consumers League (NCL) is a private, nonprofit advocacy group representing consumers on marketplace and workplace issues. We are the nation's oldest consumer organization. NCL provides government, businesses, and other organizations with the consumer's perspective on concerns including child labor, privacy, food safety, and healthcare, including medication information. Our mission is to protect and promote social and economic justice for consumers and workers in the United States and abroad.

NCL has long been involved in issues of healthcare and monitors rulemakings and legislation involving health issues, provides and participates in patient education on medication and disease awareness, and researches factors that influence the provision of medical services to patients.

NCL has worked extensively and specifically in the issues surrounding communication of information to consumers about the drugs they take. Our research, educational activities, and advocacy have included:

- Reporting upon best practices in pharmacies to protect consumer privacy;
- Consumer education on pain relievers and on aspirin therapy
- Instruction on how to read an over-the-counter drug label;
- Awareness campaign for Attention Deficit/Hyperactivity Disorder;
- Testimony regarding COX-2 inhibitors;

- Testimony regarding methamphetamine manufacture;
- Publication of a Consumer Guide To Generic Drugs and a Cholesterol Fact Sheet;
- Instruction on how consumers can avoid counterfeit drugs
- Managing SOS Rx, a coalition on safe use of drugs in the outpatient setting; and
- Information to consumers on food – drug interactions.

Furthermore, NCL is a member of the Board of Directors of the National Council on Patient Education and Information (NCPIE), a coalition of over 125 organizations whose mission is to stimulate and improve communication of information on appropriate medicine use to consumers and healthcare professionals. NCL was one of the participants on the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information – the Committee that ultimately submitted to The Honorable Donna E. Shalala an "Action Plan" (or "Keystone Report") for meeting the Public Law's targets for dissemination of useful information to patients.

NCL is pleased to submit comments on the FDA's current risk communication tools for prescription drugs, as outlined in the Federal Register Notice. While we commend FDA for undertaking this effort to improve risk information for drugs marketed and sold in the United States, we have identified several areas of concern. We will be focusing these comments on the Patient Information Sheets, and addressing some of the questions posed in the Federal Register around the following issues – coordination of all information sources, harmonization of information format and content, and communication of useful risk information.

1. Coordination of all FDA information sources

NCL believes it is vitally important for the FDA to coordinate **all** of its patient information materials. This is necessary both to avoid overloading consumers with vast amounts of potentially conflicting or duplicative information, and to ensure that the information provided is clear and readable. If the Patient Information Sheets are going to be produced for all approved drugs, even those that do not have an "emerging safety" issue, it is important that their purpose and utility is clarified. We would ask FDA to clarify the development and utility of the Patient Information Sheet, including its relationship to other written information consumers routinely receive with prescription medicines at community pharmacies.

If, however, the Patient Sheets are properly integrated with other sources, they could provide consumers with a valuable tool. Consumers would be well served, for example, by having access to a single web source with a complete (frequently updated) and consistently formatted information sheet for all medications. The sheets could be searchable by indication, class or specific product name, and would facilitate consumers' ability to compare medications across a variety of important domains.

2. Specific issues regarding the Patient Information Sheet

The FDA has specifically asked about the strengths and weaknesses of the Patient Information Sheets. While we commend the FDA for developing medication information summaries that are, for the most part, understandable and easy to read, we have noted several weaknesses.

First, we ask that the FDA ensure that each Patient Information Sheet has the same format for conveying information. The sample Patient Sheet referred to in the Federal Register for Adderall, did not contain a section on what patients should ask of their health care provider. Other sheets did not specifically contain a section on "What are the Risks" (Naproxen). It is helpful for consumers to have a similar format for each medication, so they will know what information can be expected, and that certain questions will be answered. In cases where a specific section is not relevant, it is better to have the category left blank (with notes acknowledging as much) as opposed to altering formats.

Secondly, there appears to be no mention of additional resources or references to which patients might turn for more (or related) risk and adverse event information. For example, a patient may not understand or appreciate the potential risks associated with renal failure or liver failure, and should therefore be directed to a resource where they could learn more about these risks.

Third, the Patient Information Sheets do not encourage patients to report their adverse events to the MedWatch system. Given the woefully inadequate information we have about how drug products perform on real populations once approved, FDA should be encouraging patients to use MedWatch to report their adverse events.

The current MedWatch system, which relies primarily on adverse event data reported by drug manufacturers and – to a lesser extent - physicians, is underused. FDA has admitted that the present system yields only a small percentage of the total adverse events experienced. In order to obtain more realistic rates of adverse events, the FDA should actively encourage reporting directly from patients. To achieve this, FDA needs to add a consumer portal to the existing system, and then promote the system's new features to consumers**.** As part of this effort, FDA should revamp both the telephone and Internet interfaces to make them more user-friendly, and develop a separate event report form that is easier for consumers to use.

The Patient Information Sheets provide an excellent opportunity to promote the Medwatch system**.** These Sheets could direct patients to report adverse events to their health care professional but would also provide consumers with the Medwatch Web address and toll free number to encourage direct reporting.

3. The FDA also asked in the Federal Register "Do these tools provide the right kind and amount of risk and other information that the public and health care

professionals need to make informed decisions about whether to use these products?"

a) Is this the right kind of risk information for the public?

As with all patient medication information, it is important to convey the risk information in a way that does not create unreasonable fear resulting in patients not taking needed drugs. Patients need to understand that the risk for an individual person will vary depending on whether certain risk factors are present – and their health care provider can help them determine what is right for them. However, upon reading that Advair may increase the chance of asthma death in some people, (and without a definition of who "some people" are), it is likely some patients may immediately stop taking the medication. FDA may want to consider adding a statement in the Patient Information Sheet, after the alert information, that patients should not stop or change medication until they have consulted their health care professional.

We have recently heard first hand how when risk information is misinterpreted, the results can be harmful to patients. This past October NCL held a symposium on communicating child health risks and the challenges of conveying and understanding research findings related to often-controversial child health issues. For example, we heard from physicians about their frustration when pediatric patients suddenly went off Elidel, a skin cream used to treat dermatitis that was linked with skin cancer. While the children's skin condition became much worse and they suffered tremendously, doctors were frustrated because the risk of cancer from the use of Elidel was, as FDA stated, "uncertain." There was consensus among the researchers, journalists, and others attending the symposium that all parties – including the FDA - need to do a better job of explaining that our scientific knowledge base with respect to particular drugs and diseases is never static. We are always adding to our knowledge, but have to make the best decision possible based on existing research. To help communicate this level of nuance, the Agency might wish to provide more information in the Patient Sheets about the studies that serve as the basis for the FDA alerts, and refer patients to other sources (such as the Health Care Professional Sheets and/or other partner sites that contain more detailed information on the studies). Ideally, one would like also to be able to point consumers to a centralized, NIH-managed database of all completed clinical trials – searchable by disease area, product class, and drug name. But this is a point for another set of comments.

b) Is this the right kind of risk information for health care professionals?

The health care professional should be an integral part of any patient education process, including education on medication use and associated benefits and risks. In our work with SOS Rx, a coalition of over 80 organizations focusing on improving outpatient medication safety, the health care professional is an integral part of an education campaign focusing on a high-risk medication – oral anticoagulants.

To better understand the challenges patients, clinicians and caregivers face when managing oral anticoagulants, the coalition conducted focus groups and surveys of patients on this medication, as well as clinicians and caregivers. The research revealed that there are gaps in health care management of patients on oral anticoagulants that

expose patients to serious and often unnecessary risks. Clinicians indicated that better patient information and more time spent on patient counseling could help minimize this risk. Based on this research, the SOS Rx education materials for health care professionals will be integrated with the patient materials. Patients will be educated about the key questions they need to be asking their health care professional, and, in order to respond appropriately, the health care professional will have patient education material at their disposal in order to answer their questions.

In the same way, the FDA's Patient Information Sheets must be integrated with the Health Care Professional Sheets. The Professional Sheets should specifically refer the reader to the Patient Sheets, and, most importantly, include specific questions (and answers) that the health care professionals should share with their patients – such as - do they know the risks associated with the medication? What other medications and behaviors can effect them? After reading the Patient Information Sheets, patients may very well ask the questions that are posed on the sheets, and the health care professional should be prepared to answer them for the individual patient in a way that is clear and understandable.

We remind the FDA that one of the stated goals of Healthy People 2010 is to "increase the proportion of patients who receive verbal counseling from prescribers and pharmacists on the appropriate use and potential risk of medications." Section 17.5. Prescribers and pharmacists could be encouraged to use the Patient Information Sheets as a basis for verbal counseling of their patients.

4. Finally, FDA asked for comment on the specific mechanisms it should consider using to convey risk information, particularly to special populations.

First, it is unclear how the agency plans to disseminate this information to the general public, let alone special populations. Will the Sheets be printed off at the pharmacy, given out by physicians, only accessed through the Internet? We once again ask that the FDA coordinate the dissemination of the Patient Information Sheets with other medication information.

Given that, only having access to the Patient Sheets through the Internet will limit its utility and effectiveness for some of the populations that need it most. Seniors are taking more drugs than ever, and are often on multiple prescriptions (not to mention OTCs and dietary supplements). Although Internet use is expanding, less than a third of seniors (age 65 and over) have ever gone online.[1] FDA should not just rely on the Internet – but use pharmacists, family caregivers, and health care professionals to convey information to seniors. The FDA may also want to consider running Public Service Announcements (on both radio and television) announcing the existence of a new centralized resource for consumers to get information about the prescription medications they take. The PSAs could point people to the FDA Web site, but also mention FDA partner organizations/resources that would help people get the information they need.

[1] Kaiser Family Foundation Survey of How Seniors Use the Internet, 2005.

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In closing, NCL is encouraged that FDA is seeking to improve risk communication to patients, and we appreciate this opportunity to comment.

Sincerely,

LINDA F. GOLODNER
President