Statement of Gary C. Stein, Ph.D.
Director of Federal Regulatory Affairs
American Society of Health-System Pharmacists
Before the Food and Drug Administration Public Meeting on Risk Assessment
April 9, 2003, (Docket 02N-0528)

American Society of Health-System Pharmacists®
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-652-8278
www.ashp.org

My name is Gary Stein, and I am the Director of Federal Regulatory Affairs of the American Society of Health-System Pharmacists (ASHP). ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals (including outpatient services), health maintenance organizations, long-term care facilities, home care agencies, and other components of organized health care systems. We are grateful to the FDA for calling this public workshop to receive input on the agency's approach to risk assessment of prescription drugs.

ASHP intends to provide more extensive, written comments on the FDA's approach to risk management by the April 30 deadline. Today I would like to discuss one major point.

Section III(F) of the FDA's concept paper entitled "Premarketing Risk Assessment" discusses how drug sponsors can minimize medication errors. Specifically, this section states:

> Ideally, a sponsor would conduct a risk assessment to ensure that a product's proprietary name, established name, container label, carton labeling, package insert, and/or packaging do not inadvertently contribute to medication errors. For example, a sponsor could perform a medication error prevention analysis or MEPA to ... minimize the potential for an error through corrective action including renaming, relabeling or repackaging."

The concept paper goes on to state that sponsors should assess a product's name, labeling, and packaging by obtaining "first-hand information from physicians, pharmacists, nurses and consumers." This sponsor-initiated assessment would "help to minimize medication errors" and "help speed FDA's review of these issues."

ASHP welcomes and strongly supports inclusion of this language in any future guidance document relating to premarket risk assessment issued by the FDA, and we urge the agency to quickly implement this concept. We have been encouraging FDA to do this for a long, long time:

In September 1998, we stated at an FDA Health Professional Organization meeting that drug naming, packaging, and labeling was a critical, issue that had not been adequately addressed by the FDA, despite the fact that there had been abundant evidence that poor product design is a major contributing factor in medication errors.

At a meeting in February 1999, we stated that one solution to the problem of medication errors stemming from poor package design and nomenclature is to require real-life submissions from the pharmaceutical industry prior to drug approval, and that before the FDA approves any new drug or biological product it should require manufacturers to document that it has rigorously tested all packaging, naming, and labeling for their potential to induce errors. This testing should be done using proven methods involving practicing pharmacists, physicians, and nurses in simulated work environments.

In May, 1999, we commented that the FDA has an obligation to quickly review and revise its procedures to eliminate medication errors that occur due to look-alike and sound-alike names, similarities in packaging, and other labeling and packaging problems. We also noted that patients should be considered the partners of health professionals in eliminating medication errors, and they should be involved in providing input into the safety design of drug product labeling. We are pleased that the FDA concept paper includes a provision for patient/consumer input.

In January 2002, in comments to the agency on its performance goals for the reauthorization of the Prescription Drug Marketing Act, we stated that "the most consistent message ASHP hears from its members is that the FDA should be doing more to assure that drugs are safe for patients," and that safety issues must be anticipated through premarket evaluation. One specific, new performance goal that we recommended was for the FDA to engage pharmacists, physicians, nurses, and human factors experts in documented failure-mode-and-effects analyses of prospective product nomenclature and labeling to minimize the opportunities for sound-alike names and look-alike packaging for causing medication errors.

ASHP believes that the FDA is taking the right approach to this serious public health issue and appreciates this opportunity present its comments relating to the FDA's program for risk assessment of prescription drugs.

Contact Information:

Gary C. Stein, Ph.D.
Director of Federal Regulatory Affairs
American Society of Health-System Pharmacists
7272 Wisconsin Ave.
Bethesda, MD 20814
301-657-3000, ext. 1316
gstein@ashp.org