AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS®
Pharmacists in health systems helping people make the best use of medications

September 11, 1998

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

RE: Docket No. 98N-0339: Public Meeting on Section 406(b) of the FDA Modernization Act of 1997 (FDAMA)

TO WHOM IT MAY CONCERN:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments relating to the meeting that FDA's Center for Drug Evaluation and Research (CDER) held on August 17, 1997, as part of the agency's requirement under section 406(b) of FDAMA to consult with external stakeholders prior to its development of a plan for achieving compliance with its statutory obligations under the Food, Drug, and Cosmetic Act. ASHP is the 30,000-member national professional association representing pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care organizations, and other components of health care systems. ASHP specifically offer comments on 3 of the 6 questions posed by CDER in a July 21, 1998, communication to "CDER Stakeholders."

1. **Drug Marketing and Advertising**. CDER asked, "How can CDER ensure that drug promotion is both balanced and non-misleading?"

   A simple summary of our answer is that we are not certain this can be done, given the nature of promotional messages and the nature of prescription drugs. ASHP supports consumer access to full information about all medicines. We believe, however, that for best understanding by most patients, this information must be interpreted for them by learned professionals, including physicians and pharmacists. ASHP continues to believe that promotional advertisements for specific drug products ultimately pose significant risk to patients. They also burden the health-care delivery process with partially informed patients and, often, unrealistic patient expectations induced by the advertisements. ASHP supports direct-to-consumer advertising that is educational in nature about the availability of prescription drug therapies for certain medical conditions, but we oppose direct-to-consumer advertising of specific prescription drug products.

   This policy reflects the awareness of health-system pharmacists that direct to-consumer advertisers tend to minimize the risks associated with the drug product being advertised.

   This is in contrast to the more prominent attention given to the benefits attributed to the use of the product. ASHP believes that, given their brevity, direct-to-consumer broadcast advertisements cannot provide consumers with adequate risk/ benefit information on prescription medicines. In that sense, they are inherently misleading.

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Greater opportunity for full information obviously exists with printed advertisements. We believe it is unrealistic, however, to imagine that the mere printing of "package insert" information along with a promotional advertisement provides appropriate interpretive information for consumers.

Health-system pharmacists have observed a greater tendency toward self-diagnosis by consumers and more frequent patient requests for prescriptions for advertised drug products. We believe there is a real danger that this eventually will lead to the prescribing of inappropriate medications. This country has a class of prescription-only medicines because the public believes that certain medicines require professional expertise in deciding when and how to use them. The concept of enticing the public to seek prescriptions for those medicines simply cannot be reconciled with the concept of restricting the medicines' availability for public safety reasons.

Given the depth of information and interpretation essential to the appropriate use of prescription medicines, we are not convinced that advertisements for specific drug products can ever be anything but somewhat misleading. We urge the FDA to seek the resources necessary to appropriately manage the task of monitoring direct-to-consumer advertising of prescription medications.

2. **Drug Information.** CDER states that it is "an authoritative and independent source of drug information" and asks, "How can we assure that health professionals and consumers get the information they need about drugs?" While FDA's authoritativeness and independence with respect to drug information is acknowledged, it must be observed that this expertise is greatest with respect to (1) the original indications proposed by drug product manufacturers as part of their applications for marketing approval and (2) post-marketing surveillance information. Entities outside the FDA, however -- including ASHP -- are also authoritative and independent sources of drug information. Importantly, some of these sources -- including ASHP -- give broader attention to all scientifically and clinically established drug uses. Ultimately, health professionals and consumers need information about both the uses that qualified a drug product for initial marketing as well as other legitimate uses.

   Dealing narrowly, however, with how CDER can best provide the information it <u>does</u> have to professionals and consumers, we can imagine several possible ways:

   a. Continue to make "package insert" information available via the World Wide Web. ASHP is aware of FDA's resolve to make these accessible for "new, innovator drugs approved by FDA since January 1998" (quoting from FDA's Web-site information). This is commendable, but we believe similar access should be devised for drug products approved before that date as well.

   b. Provide a fax-on-demand service for access to "package inserts," post-marketing surveillance data, and special alerts.

   c. Provide a widely publicized hot line for telephone access to information by professionals and consumers.

ASHP is also aware of FDA's new Consumer Information section in its Web site, which promises to provide consumers with information for all newly approved drug products. However, unless this information can be expanded and kept up to date with respect to unlabeled uses, we question its long-term utility in meeting patients' needs.

The FDA has made great strides in providing information via both the Web and CDER's fax-on-demand service. The timely posting of special alerts on the Web has improved noticeably in the past couple of years, and these notices have been gratefully received by pharmacists. Automatic e-mailing of such information to various organizations that can then multiply transmission to their constituents has also been very helpful. Links between the FDA Web site and others also has been appreciated.

3. **Surveillance and Adverse Event Reporting.** CDER asked, "What else needs to be done to detect, analyze, communicate, and respond to the causes of death and injury from medicines?" ASHP believes that the FDA should play a larger role in helping this nation improve the safety of medication use. The agency readily has at hand, through the MedWatch program and through its oversight of labeling and packaging in the approval process, powerful tools to achieve this goal, and we strongly encourage it to use these tools.

   First, ASHP encourages FDA to consider ways to allow anonymous reporting to the MedWatch program. We fully recognize FDA's current commitment to confidentiality with respect to reported data and the value of being able to contact reporters for more information, but we believe the promise of confidentiality is not sufficient to erase the fear of legal discoverability of reported information. As a related development, as of July 1998, hospitals can now report errors anonymously via the Internet through the MedMARx program operated by the United States Pharmacopeia.

   From time to time, FDA has issued MedWatch communications about specific problems. These are very helpful to health professionals. If there is not a standard schedule for release of these communications, however, we suggest that there be a scheduled distribution of summaries of these several times per year. Special-alert notices still might be needed in urgent circumstances.

   ASHP is aware of the efforts of the National Coordinating Council on Medication Error Reporting and Prevention (NCC MERP), with FDA's good input, to develop a standardized taxonomy of reportable events. We applaud FDA's efforts to foster this and encourage FDA's formal adoption of such a standardized taxonomy if it evolves.

   In addition to health-system pharmacy's long-standing attention to the prevention of medication misadventures, substantial increased attention to this is recently occurring through various groups, including NCC MERP, the National Patient Safety Foundation, the Institute for Healthcare Improvement, The Department of Veterans Affairs, the Joint Commission on Accreditation of Healthcare Organizations, the Institute for Safe Medication Practices, and the American Association

for the Advancement of Science. We anticipate that many constructive recommendations and initiatives will emerge through these efforts. Among them may be an effort to standardize definitions for terms such as "medication errors," "adverse drug reactions," and "adverse drug events." We encourage FDA to remain open to the possibility of refining its definitions if this evolves.

To support the research of others, we encourage the continued access by others to the MedWatch database (with appropriate shielding of confidential aspects of the data). The MedWatch database represents a growing "mine" of information that researchers might use in analyzing medication-error problems and then constructing appropriate solutions.

ASHP understands that the FDA may be planning to substantially increase the resources it devotes to this important program. As it does so, we encourage the agency to find a way to bring its MedWatch reports to the direct attention of practicing pharmacists, physicians, and nurses. We also encourage the agency to make analysis of MedWatch data a priority in order for the health care professions to learn as much as possible from the reports received. The agency should also bring to the attention of health professions practical advice on steps they can take to reduce problems associated with specific products.

In the cumulative reports of medication errors there is abundant evidence that poor product design is a contributing factor in many medication errors. Poor label readability, poor nomenclature, look-alike and sound-alike product names, confusing abbreviations, and a lack of machine-readable bar coding are all examples of product-designs that contribute to errors. These problems are increasing because of the high-stress environments in which a growing number of health professionals practice. The projected escalation in approvals of new drugs, biologics, and drug-related devices will also exacerbate the problem. One of the speakers at the FDA-sponsored meeting on "Minimizing Medical Product Errors" in January of this year noted that 20-25% of reported medication errors result from look-alike or sound-alike drug nomenclature which cause patient injury because of confusion in the process of ordering, dispensing, or administering medications.

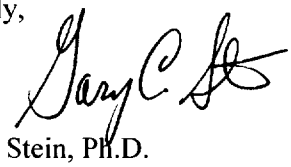
The FDA is well aware of these problems and the errors they can lead to. Almost exactly two years ago, one of the Center for Drug Evaluation and Research meetings with representatives of health professional organizations was devoted to the topic of medication errors. At that meeting, an FDA speaker noted that the agency was considering some specific proposals that would aid in remedying the product design problems. One solution that was mentioned was to require real-life submissions from the pharmaceutical industry -- final product labels and actual market packaging -- prior to drug approval. Another solution proposed was that the agency would review all proposed trade names. Still another proposal was that labeling regulations be simplified to eliminate all unnecessary information. The most promising proposal contemplated a failure mode and effects analysis as part of the New Drug Application safety summary.

What has happened since that meeting two years ago? Apparently, not much. As of two weeks ago, ASHP was informed that the agency was "still considering its options." It is time to stop considering options and take substantive action. Patients are being harmed because of the agency's inaction. Before the FDA approves for marketing any new drug or biological product, it should require the manufacturer to document that it has rigorously tested all packaging and labeling for their potential to induce errors. This testing should be done using proven methods involving practicing pharmacists, physicians, and nurses in a simulated work environment. Such failure mode and effects analyses have been applied successfully in the nuclear power industry and in aviation to help prevent small errors from becoming large catastrophes. We strongly encourage the FDA to require that this proven technique be applied to drug products; until the agency does so, it will be compromising its responsibility in consumer protection.

Further, for the list of pharmaceutical products currently on the market whose packaging and labeling have been documented to cause errors, the FDA should initiate an assertive process to require the manufacturers to make the appropriate changes.

ASHP appreciates the opportunity to respond to the FDA's request for comments on its obligation under Section 406(b) of FDAMA to develop a plan for the agency to meet its statutory mission to protect the public health. Feel free to contact me if you have any questions regarding our comments.

Sincerely,



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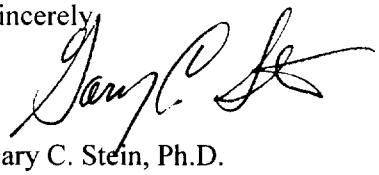

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