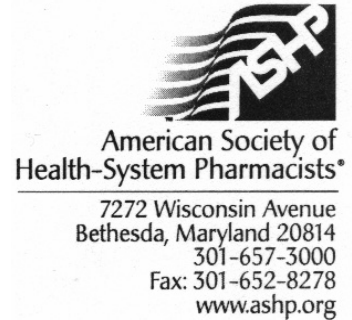


February 23, 2007



Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852.

**Docket No. 2005N-0005: Prescription Drug User Fee Act; Public Meeting**

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on its proposed recommendations for reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FY) 2008 to 2012. ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals and other components of health care systems. ASHP members practice in hospitals and integrated health systems where they are involved in many phases of the medication-use process, promoting public health by fostering safe and effective use of medicines in hospitals and health systems.

While ASHP is pleased that the PDUFA program continues to support the FDA's mission to protect and promote public health, we believe that the next reauthorization must go much further in this regard. As PDUFA has allowed faster drug approvals, manufacturers must bear some of the responsibility to provide support for drug safety initiatives. We are pleased that the reauthorization proposed by the FDA makes new strides in this regard.

As we noted in our PDUFA comment letter submitted in December 2005, critical elements of this reauthorization must include: 1) improved postmarketing safety regulation, 2) address the impact of direct-to-consumer advertising on medication-use safety, and 3) develop models of patient care that bring actual medication use into better alignment with medication-safety information. We believe that FDA's recommendations do attempt to address these key areas however some additional improvements can be made:

**Premarket Risk Assessment**

- **Restricted Drug Distribution**- The agency's recommendations pay considerable attention to improving the availability of information for manufacturers on trial design and the timeliness of product labeling and postmarketing commitment discussions. While these are critical elements of an efficient and effective premarket risk assessment program, what is lacking in this proposal is a plan to establish clear guidance and policy regarding manufacturer development of restricted drug distribution systems (RDDS).

ASHP has policy approved by its Board of Directors to address many concerns with the existing RDDS framework (see attached policy). As we have suggested previously, ASHP suggests that this PDUFA reauthorization provide for research on how well existing and new restricted drug distribution systems are achieving their goals. Additionally, new PDUFA reauthorization legislation should mandate that drug manufacturers and the FDA partner with professional organizations in conducting this research.

The Society also recommends that this PDUFA reauthorization direct the FDA Drug Safety and Risk Management Advisory Committee to craft recommendations to improve RDDS programs. The committee should analyze current FDA standards and recommend new policy in several key areas related to RDDS including: 1) feasibility of standardizing basic elements of all programs, 2) ensuring timely access to drugs for patients, 3) eliminating continuity of care problems, and 4) permitting exceptions from various RDDS program registration rules for those practitioners that meet predetermined agency standards and requirements. We would also encourage the Committee to be engaged in the stakeholder's conference that the agency has said it is planning on this topic. As the lead committee tasked with advising the Commissioner on risk management, this group is well equipped to assist the agency in developing new policy that would improve the management and oversight of RDDS programs.

### **Postmarketing Surveillance**

The Society has long standing policy which supports increased authority for the FDA to mandate postmarketing safety studies (see policy #0515). ASHP supports the Agency's recommendation to eliminate the statutory restrictions so that PDUFA fees could be used to assess safety issues postapproval, independent of a product's approval date and allow the agency to review the drug's safety in whatever time frame risks arise using all available resources. There are a few elements of FDA's postmarket recommendations where we would suggest some changes:

- Adverse Event Reporting and Assessment- We are pleased to see a recommended initiative to conduct research on maximizing the public health benefits associated with collecting and reporting adverse events throughout a product's life cycle. Additionally, we support access to population-based data to utilize signal detection as part of improved post marketing surveillance. Pharmacists are especially positioned to provide leadership in medical error reporting programs and we would urge the agency to include these health care professionals in its research efforts to improve the use of adverse events data that are collected and reported.

- Drug Naming and Labeling- ASHP is pleased that the agency is recommending the development of new guidance materials to improve methods for naming and labeling drugs. With respect to measures to reduce medication errors related to look-alike and sound-alike names, we support the recommended pilot program to explore a different paradigm for proprietary name review. The agency recommends publishing three guidance documents in this area including: naming, labeling, and packaging. We urge the inclusion of pharmacists as part of the agency's consultation in developing this guidance. In addition, we recommend that FDA tap the expertise of human factors scientists who can provide the needed perspective.
- Effective Risk Communication Strategies- While we are pleased that FDA has recommended expanding the types of tools available for adverse event detection, this will have only limited impact if risk information is not made available to the public in some way. As we have stated in earlier correspondence, the agency could benefit from a research program examining methods and mechanisms for effective risk communication by health professionals, including looking at who -- pharmacists, physicians, industry, etc. -- and where -- in the pharmacy, by telephone, via DTC -- such communication is most effective.

**Direct-to-Consumer Advertising-** ASHP has long advocated for FDA to develop research to evaluate the medication use safety implications of FDA policies and industry marketing practices related to direct-to-consumer (DTC) advertising of prescription medicines. We believe that the recommendations included in PDUFA IV in this area fall short. Data on the impact that DTC ads have on the appropriateness of medication use remains negligible. ASHP members have also supported policy that promotes delays in DTC promotion until postmarketing data are collected and assessed (see attached policy #0609). ASHP suggests that in combination with this delay, it would be consistent with the FDA's public health mission for the agency to commission research on this topic.

**Innovations in Health Care Practice-** In order to fully address medication safety, it is critical to allot dedicated research funds to study innovations in health care practice that may improve the safety of medication use. Insufficient attention is given to evidence about how to use a medication safely, and by ignoring this critical element of research the government continues to miss an opportunity to identify and solve a significant portion of the drug safety problem. ASHP would encourage the FDA to expand its research base through PDUFA reauthorization, dedicating funds to research in this important area of drug safety.

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ASHP appreciates this opportunity to present its comments on PDUFA reauthorization to the FDA. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8698, or by e-mail at [bmeyer@ashp.org](mailto:bmeyer@ashp.org)

Sincerely,

A handwritten signature in black ink, appearing to read "Brian M. Meyer". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Brian Meyer  
Director, Government Affairs Division

## ASHP PDUFA-Related Policies

### **RESTRICTED DISTRIBUTION SYSTEMS REVISED POLICY FOR THE HOUSE OF DELEGATES**

*Source: Council on Legal and Public Affairs*

**This policy has been approved by the ASHP Board of Directors and is subject to review by the ASHP House of Delegates when it meets in June 2007.**

To affirm support for the current system of drug distribution in which prescribers and pharmacists exercise their professional responsibilities on behalf of patients; further,

To acknowledge that there may be limited circumstances in which constraints on the traditional drug distribution system may be appropriate if the following principles are met: (1) the requirements do not interfere with the continuity of care for the patient; (2) the requirements preserve the pharmacist-patient relationship; (3) the requirements are based on scientific evidence fully disclosed and evaluated by prescribers, pharmacists, and others; (4) there is scientific consensus that the requirements are necessary and represent the least restrictive means to achieve safe and effective patient care; (5) the cost of the product and any associated product or services are identified for purposes of reimbursement, mechanisms are provided to compensate providers for special services, and duplicative costs are avoided; (6) all requirements are stated in functional, objective terms so that any provider who meets the criteria may participate in the care of patients; and (7) the requirements do not interfere with the professional practice of pharmacists, prescribers, and others; further,

To advocate that the Food and Drug Administration (FDA) be granted the authority to consult with practicing pharmacists and others when the establishment of a restricted distribution system is contemplated for a drug product; further,

To advocate that the FDA be granted the authority to require that manufacturers disclose all of the considerations that led to the establishment of a restricted distribution system for a specific product; further,

To advocate that the FDA be granted the authority to require that manufacturers include in each restricted distribution system a mechanism that will ensure medication reconciliation and continuity of care as patients transition from one level or site of care to another; further,

To advocate that the FDA be granted the authority to require manufacturers to conduct a follow-up assessment of the impact of a restricted drug distribution system.

**0515**

**POSTMARKETING SAFETY STUDIES**

*Source: Council on Legal and Public Affairs*

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,

To advocate that Congress grant FDA broader authority to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA to fulfill this expanded mission related to postmarketing surveillance.

**0609**

**DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION AND  
NONPRESCRIPTION MEDICATIONS**

*Source: Council on Legal and Public Affairs*

To support direct-to-consumer advertising that is educational in nature about prescription drug therapies for certain medical conditions and that appropriately includes pharmacists as a source of information; further,

To support direct-to-consumer advertising of specific prescription drug products *only* when the following requirements are met: (1) that such advertising is delayed until postmarketing surveillance data are collected and assessed, (2) that the benefits and risks of therapy are presented in an understandable format at an acceptable literacy level for the intended population, (3) that such advertising promotes medication safety and allows informed decisions, and (4) that a clear relationship between the medication and the disease state is presented; further,

To support the development of legislation or regulation that would require nonprescription drug advertising to state prominently the benefits and risks associated with product use that should be discussed with the consumer's pharmacist or physician.