

Senate HELP Committee

hearing on

User Fees: Enhancing Patient Access  
and Drug Safety

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Statement for the Record  
Submitted by the



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The American Society of Health-System Pharmacists (ASHP) respectfully submits the following statement for the record to the Senate Health, Education, Labor and Pensions (HELP) Committee hearing on “User Fees: Enhancing Patient Access and Drug Safety”.

ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient outcomes. This includes working with patients to help them access the medications they need and to use them safely and effectively.

The Society has long-standing policies that express support for Congressional action to provide the Food and Drug Administration (FDA) with increased authorities to require post-marketing studies on the safety of drugs that are in the public interest. ASHP policy has also supported broader authority for the FDA to require additional labeling or the withdrawal of certain products on the basis of review of such studies.

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 of the Prescription Drug User Fee Act (PDUFA) will address this issue, targeting resources to modernize the post-market drug safety system.

As we noted in our comments to the FDA early in the reauthorization process, critical elements of this reauthorization must include: 1) improved post-marketing 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 and we ask the Committee to consider several points as it pursues a legislative strategy:

### **Premarket Risk Assessment**

#### **Restricted Drug Distribution**

There are many concerns regarding the existing restricted drug distribution system (RDDS) framework. RDDS programs are developed for many reasons, most importantly to ensure that drugs with very high risks are prescribed, dispensed and administered safely. While these systems are necessary in appropriate circumstances to protect patients, there are many challenges associated with their administration, especially in the hospital setting, which compromise the quality of patient care.

ASHP recently conducted a survey (see attached) of its members who have experience with RDDS to better understand what hospital pharmacists and their patients are experiencing with regard to these programs. ASHP received 521 responses from

hospitals and health-systems nationwide with 49 states represented. Most significant findings indicate that timely access to drugs for patients and care continuity are frequently or occasionally a problem in the vast majority of hospitals and health-systems. The findings also indicate that most hospital and health-system pharmacists believe that some aspects of RDDS programs can be standardized.

The reauthorization of PDUFA provides a unique opportunity to improve elements of FDA's oversight of these programs, improving patient care and reducing unnecessary burdens on the health care system. 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.

### **Postmarketing Surveillance**

ASHP supports the elimination of 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. The Society does ask the Committee to consider the following as it drafts its final PDUFA proposal:

Adverse Event Reporting and Assessment- ASHP was pleased to see that the FDA's draft recommendations included an 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 medication error reporting programs and we would urge the Committee to require FDA 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 FDA's draft recommendations suggest 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 Committee to require the inclusion of pharmacists as part of the agency's consultation in developing this guidance.

Effective Risk Communication Strategies- While we are pleased that FDA has suggested a draft recommendation to expand 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. ASHP would suggest that the Committee include in its PDUFA proposal a new research program which would examine 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 FDA's draft recommendations for 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. 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 Committee to expand FDA's research base through PDUFA reauthorization, dedicating funds to research in this important area of drug safety.

### **Conclusion**

We appreciate the opportunity to share our views on aspects of the PDUFA reauthorization. It is essential that the American public have confidence in our nation's ability to maintain the integrity of our drug supply and protect patient health through appropriate drug approval and monitoring systems. ASHP and its members are committed to working with the Congress, FDA and other stakeholders to achieve this goal.