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American Society of Health-Systems Pharmacists
Food and Drug Administration
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Prescription Drug User Fee Act

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Good afternoon, my name is Brian Meyer and I am the Director of Government Affairs at the American Society of Health-System Pharmacists (ASHP). ASHP represents over 30,000 pharmacists and pharmacy technicians who practice in a variety of health system settings, including inpatient, outpatient, home care, and long-term-care settings. I appreciate the opportunity to present the views of ASHP on the agency's recommendations for PDUFA IV.

At the outset, ASHP has broad policy in support of FDA's public health mission and believes that the agency should be appropriated ample funds to conduct that mission. However, we recognize that reliance on user fees is unlikely to change in the foreseeable future. While ASHP is pleased that the PDUFA program continues to support the FDA's mission, we believe the next reauthorization must go much further. As PDUFA has allowed faster drug approvals, manufacturers must bear some of the responsibility to provide support for drug safety initiatives.

I will provide some brief comments in three areas of the agency's proposed recommendations for reauthorization of PDUFA. These include pre-market risk assessment, post-marketing surveillance and direct-to-consumer advertising.

In the area of pre-market risk assessment, the agency's recommendations highlight the need to improve the availability of information during this phase of a product's lifecycle. However, ASHP would urge the agency to also establish clear guidance and policy regarding manufacturer development of restricted drug distribution systems (RDDSs). ASHP recommends that PDUFA establish new research to determine how well existing and new RDDSs are achieving their goals. Moreover, ASHP's members' experiences indicate the need for PDUFA to mandate that drug manufacturers and the FDA partner with professional organizations in conducting this research.

The Society would also suggest that PDUFA authorize the establishment of a new advisory committee, tasked with crafting recommendations to improve RDDS programs. This committee

would 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 pre-determined standards and requirements.

In the post-marketing area, ASHP supports the agency's recommendation to eliminate the statutory restrictions so that PDUFA fees could be used to assess safety issues 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.

We are also 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 lifecycle.

ASHP also supports the development of guidance on epidemiology best practices to aid in evaluating drug safety. Additionally, we support access to population-based data to utilize signal detection as part of improved post-marketing surveillance.

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 this pilot and the agency's consultation in developing this guidance. In addition, we recommend that FDA tap the expertise of human factors scientists who can provide that needed perspective.

In the area of 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 DTC advertising of prescription medicines. We believe that the recommendations included in PDUFA IV in this area fall short. ASHP's policy supports a delay in DTC promotion until post-marketing data are collected. ASHP suggests that in combination with this delay, the agency commission research on the impact of these advertisements on the appropriateness of a medication's use.

Finally, ASHP feels that dedicated funds should be used to research innovations in health care practice that may improve the safety of the medication use system and the lifecycle of a drug product. Researching this critical element may solve a significant portion of the drug safety problem.

Thank you for the opportunity to present these comments.