



American Society of  
Health-System Pharmacists<sup>®</sup>  
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July 24, 2006

The Honorable Mike Enzi  
Chairman  
Health, Education, Labor and Pensions Committee  
835 Hart Senate Office Building  
Washington, DC 20510

The Honorable Edward M. Kennedy  
Ranking Member  
Health, Education, Labor and Pensions Committee  
644 Dirksen Senate Office Building  
Washington, DC 20510

Dear Senators Enzi and Kennedy:

Thank you for providing an opportunity to comment on your draft legislation, the “Enhancing Drug Safety and Innovation Act of 2006”. We are pleased to provide input on behalf of our members and commend you for your efforts to improve drug safety for all Americans.

For more than 60 years, the American Society of Health-System Pharmacists (ASHP) has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. ASHP’s 30,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term care settings, and pharmacy students. ASHP and its members have a significant stake in the issues addressed by your legislation and share your view that the current drug safety system must be improved.

While increased regulation is essential, it is also important to recognize that no system will succeed without the commitment and proper training of health care professionals and the understanding by patients of medication risks and benefits. As you move forward with this legislation, we would urge you to continue to evaluate the essential role that health care professionals and especially pharmacists play in ongoing post-marketing surveillance and in managing known risks. As medication-use experts and frontline providers of medication management services, pharmacists are necessary and fundamental to the drug safety system, with a responsibility to assist patients, physicians, and other health care professionals.

We are pleased to provide the following comments on your draft legislation:

*Serving pharmacists in hospitals and health systems*

## **Title I-Drug Safety**

ASHP supports the legislation's intent to develop a planning and surveillance system that will ensure that new safety information about a drug is integrated into current post-approval oversight in order to adequately manage risk. The Society has long-standing policies that advocate for Congress 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.

ASHP supports the use of Risk Evaluation and Mitigation Strategies (REMS) to guide the acquisition and adaptation of new safety information about a drug. While we support the legislation's intent to require additional elements in a drug's REMS should there be increased safety concerns, we would suggest that you consider making a few modifications to this section:

- Should an applicant develop non-promotional labeling for patients and providers, we would suggest the FDA review and approve these materials before they are disseminated to ensure that they are balanced and without bias.
- Any communication plan directed to physicians should also be directed to pharmacists. Including pharmacists in the communication plan is especially important in supporting implementation of black box warning in labeling and the implementation of restrictions on distribution and use.
- Mandate that the FDA standardize and minimize the types of restricted distribution systems, in collaboration with various stakeholders, including pharmacists who practice in hospitals and health systems. Highly varied systems of this type do not always take into account the use of medication in health care institutions, and as a result, patient care can be put at risk. In an ASHP survey conducted in May 2006, members indicated that cumbersome paperwork and time-consuming compliance requirements of some restricted distribution systems have resulted in pharmacists having significant difficulty coordinating therapy; further, pharmacists said that they often lack information about the patient's overall therapy under such systems.

Should a REMS require additional elements due to increased safety concerns, we would suggest that the proposed REMS be aired for public comment. ASHP believes that this would be especially important should restrictions on distribution and use be included in a REMS proposal. We would also recommend that when the REMS is reviewed annually it also be subjected to a period of public comment. Public input would allow health professionals and experts to review the proposed REMS and provide valuable information from a clinical perspective.

Finally, ASHP recommends that FDA staff responsible for a drug approval not be permitted to have the responsibility for also reviewing and approving a proposed REMS for that same drug.

## **Title II- Reagan-Udall Institute for Applied Biomedical Research:**

ASHP supports your efforts to enhance applied biomedical research to improve drug safety and effectiveness. We have long advocated for the promotion of various public-private sector

models to combine the talent and expertise of the federal government and private sector in order to meet research needs in the area of prescription drugs.

While we do acknowledge that better tools to evaluate drugs are an essential component of improving drug safety, it is important to consider that actual practice patterns and behaviors of prescribers, and the treatment-regimen-adherence behaviors of patients, are a significant factor in promoting drug safety.

We would encourage the expansion of the Institute's activities to include the study of how knowledge regarding the safe and effective use of specific high-risk medicines can be applied most effectively in patient care, including through the establishment of collaborative practice arrangements between prescribers and drug information experts and by improved communications between health professionals and patients.

ASHP would also highly recommend that the Institute Board of Directors include clinical practitioners from the professions of medicine and pharmacy.

### **Title III- Clinical Trials Registry and Clinical Trials Results Database**

ASHP policy supports the disclosure of the most complete information possible on the safety and efficacy of drug products and has recommended the establishment of a mandatory results registry for all Phase II, III and IV clinical trials that are conducted on drugs intended for use in the United States. All clinical trials undertaken, but not yet completed, should be added to the registry and, upon completion, the results should be posted electronically with unrestricted access as quickly as possible after FDA approval but before marketing commences. Strong enforcement mechanisms are necessary to ensure compliance.

Thank you for the opportunity to comment on this draft legislation. ASHP is willing to collaborate with all interested parties in an open and fully engaged process to improve medication safety in the United States. If you or your staff have any questions, please feel free to contact Mara Baer, Director, Federal Legislative Affairs at 301/664-8710.

Sincerely,



Henri R. Manasse, Jr., Ph.D., Sc.D.  
Executive Vice President and Chief Executive Officer