

April 30, 2007

The Honorable Edward Kennedy  
The Honorable Mike Enzi  
Committee on Health, Education, Labor and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510



Dear Chairman Kennedy and Senator Enzi:

The American Society of Health-System Pharmacists (ASHP) would like express its support for the Food and Drug Administration Revitalization Act (S. 1082) as reported out by the Committee. Enhancing the safety of our drug supply is an important issue to our Society and we commend your efforts.

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.

The Society has long-standing policies which support many of the goals outlined in your legislation which include:

- Increased authorities for the Food and Drug Administration (FDA) to require a manufacturer to conduct post-marketing studies on the safety of a product when the agency deems it to be in the public interest and require any additional labeling if appropriate,
- The establishment of a mandatory results registry for all Phase II, III, and IV clinical trials and that this information be made publicly available,
- Increased oversight of direct-to-consumer advertising of specific prescription drug products to protect the public health and promote safety,
- Promoting efforts to ensure that patient access and continuity of care are not compromised within restricted drug distribution systems (RDDS), and advancing the role of pharmacists in the assessment process for RDDS systems.

As you move forward with this legislation, ASHP members would support any efforts to expand this legislative package to include development of a pathway for approval of biogenics. The Society has approved the following policy that which expresses support for biogeneric approvals:

To encourage the development of safe and effective generic versions of biologic medications in order to make such medications more affordable; further,

To encourage research on scientific methods to ensure the safety, effectiveness, and therapeutic equivalence of generic biologic medications; further,

To support legislation and regulation to allow Food and Drug Administration approval of generic versions of biologic medications.”

ASHP supports your efforts to improve the drug safety system in this country. While this legislation is a critical step forward, increased federal regulations of drug approval, marketing and surveillance alone will not achieve the overall improvements needed in our drug safety system. It is important that Congress 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 hope that you do all you can to maintain the provisions currently outlined in S. 1082. ASHP believes that the areas addressed in the legislation go a long way to address many of the issues of our drug safety system today. Of course, many additional enhancements are necessary to ensure the most secure system possible, and our members stand ready to work with Congress to continue to promote such an agenda.

Should you have any questions about ASHP policies, please feel free to have your staff contact Mara Baer, ASHP Director of Federal Legislative Affairs at 301-664-8710 or by e-mail at [mbaer@ashp.org](mailto:mbaer@ashp.org).

Sincerely,



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