

Senate HELP Committee

hearing on

Building a 21st Century FDA:
Proposals to Improve Drug Safety and Innovation

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Statement for the Record
Submitted by the



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Serving pharmacists in hospitals and health systems

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 “Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation”.

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.

ASHP applauds Chairman Enzi and Senator Kennedy for their efforts to try and address the difficult challenge of establishing a system of drug approval and monitoring that maintains a balance between the benefits of an innovative, potentially life-saving drug and the risks associated with its widespread use in the population. The current drug safety system can be improved through increased regulation, but it is important to realize that no system will succeed without the commitment and proper training of health care professionals and the understanding of patients of medication risks and benefits.

As you move forward with legislation to address drug safety, 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.

As the Committee pursues its legislative strategy, we would ask that you consider several points in key areas:

Post-Marketing Surveillance Strategy & Restricted Drug Distribution Systems

The “Enhancing Drug Safety and Innovation Act” (S. 3807) does permit the establishment of new Restricted Drug Distribution Systems (RDDS) in some limited circumstances. While ASHP values and acknowledges the critical role that an RDDS plays in managing drug safety, the use of such systems should not compromise timely and appropriate patient care and should not be overly burdensome to health care practitioners who are attempting to meet patient needs. This is especially of concern in hospital settings where pharmacists are trying to deliver medications and manage the therapy for high-risk patients.

While we understand that new RDDS programs will only occur in limited circumstances, they do have a cumulative effect on health-system pharmacy practice and patients directly. Many ASHP members have reported that RDDS programs are burdensome and confusing for practitioners and that they at times result in delayed care and inconvenience for patients and disrupt the continuity of care.

In order to simplify these programs while maintaining their intent, we urge the Committee to work with ASHP and other stakeholders to develop legislation that would standardize RDDS programs, require pharmacist input into each program's development, and improve access to information for clinicians and patients about the types of restricted distribution systems.

Direct-to-Consumer Advertising

ASHP policy supports direct-to-consumer advertising of drug products only when the following requirements are met: 1) such advertising is delayed until post-marketing surveillance data are collected and assessed, 2) the benefits and risks of therapy are presented in an understandable format at an accepted 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.

While ASHP is pleased to see that S. 3807 permits FDA to place certain requirements on manufacturers' drug advertising efforts, we would recommend that the Committee permit the FDA to extend any moratorium period over 2 years should additional delays be required to collect and assess essential post-marketing surveillance data.

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.

Additional FDA Funding Needed for Post-Marketing Surveillance

While we acknowledge funding is not in the jurisdiction of this committee, we cannot discuss enhancing FDA's ability to meet its public health mission without expressing support for increased resources for the agency. It is startling that the resources designated to for all food and drug regulatory activities in the United States are equivalent to the budget of the Montgomery County, Maryland, public school system (\$1.85 billion for 2007), which is the county where the agency is located. ASHP is a member of the FDA Alliance and supports funding increases for the agency for the 2008 fiscal year.

Better Utilization of Pharmacists Should Be Fostered

Increased federal regulations of drug approval and marketing alone will not result in an improved drug safety system. We urge the Committee to look carefully at methods to better prepare health care professionals for playing a larger role in post-marketing surveillance and in managing known risks. ASHP believes pharmacists have a crucial role in fostering improved medication-use safety. Postgraduate pharmacy residency training is especially designed to prepare pharmacists for this role. Unfortunately, there are an insufficient number of such accredited programs to meet the nation's needs. Additional federal support for pharmacy residency training would have a major effect on improving the outcomes from medication use, especially in high-risk patients.

As medication-use experts and frontline providers of medication management services, pharmacists are necessary and fundamental to the drug safety system. All medications have associated risks, and pharmacists have a responsibility to assist patients, physicians, and other health care professionals in managing medicines with risk profiles that require careful patient selection and monitoring. Products that are safe and effective only in certain patients but not in others have been withdrawn from the market due to inappropriate management of well-known risks and a lack of ability to differentiate appropriately among patients. If a pharmacist, as part of the health care team, had monitored and adjusted the therapy to minimize or eliminate risks, a subset of patients could have continued to receive benefits from the withdrawn medications.

Conclusion

We appreciate the opportunity to share our views on how to improve the drug safety system in this country. 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.