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American Society of  
Health-System Pharmacists®

7272 Wisconsin Avenue  
Bethesda, Maryland 20814  
301-657-3000  
Fax: 301-664-8877  
www.ashp.org

February 4, 2008

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. 2007N-0489, Comments Pertaining to the Science and Technology Report**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology* (the Report). The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP commends the Subcommittee on Science and Technology (the Subcommittee) for its comprehensive report. ASHP policy supports the FDA's public health mission of ensuring the safety and effectiveness of drugs, biologics, and medical devices through risk assessment, appropriate product approval, labeling approval, manufacturing, oversight, and consultation with health professionals.

**Need for Increased Funding**

ASHP recognizes that FDA is hindered in carrying out its public health mission by the lack of available resources, and the Society agrees with the overarching finding of the Subcommittee that the FDA has experienced decreasing resources in the face of increasing responsibilities. Of particular note to ASHP is the fact that the Subcommittee was asked to review gaps in scientific expertise and technology and not to assess available resources. Nevertheless, the Subcommittee found that the gaps were so intertwined with inadequate funding, that it was impossible to assess technology without also assessing resources. The Subcommittee recommended that the FDA resource gap must be corrected to enable the Agency to fulfill its regulatory mandate.

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ASHP firmly believes that increases in FDA resources are necessary, and these increases should be made available and funded through federal appropriations, rather than through user fees. As an active member of the Alliance for a Stronger FDA (the Alliance), ASHP was pleased to see the fiscal year 2008 appropriations funding increases provided to the agency through the congressional appropriations process, and ASHP will continue to work with the Alliance to advocate for further increases in funding for the Agency. We strongly encourage FDA leaders to work assertively through the federal budget process to increase budgetary requests to Congress.

### **Improving Drug Safety**

The Society was pleased to see the Subcommittee recommend that FDA should immediately implement the Institute of Medicine recommendations for improving drug safety, and that FDA should strengthen the information tools for supporting effective risk assessment. The Society agrees with the Subcommittee that the key areas of focus would include providing improved database access and analysis in support of safety assessment, including access to health and public health databases for adverse-event identification and surveillance for risk identification and evaluation. ASHP supports the development of advanced data mining and analytical methodologies for signal detection in large health care databases. In addition, early signals about a product's safety should be transmitted in an electronic format for use by credible private sector drug information compendia to support the provision of up-to-date and timely information to frontline health care professionals on drug safety matters.

ASHP agrees with the Subcommittee's recommendation that FDA should institute more opportunities for cross-Center and interagency interaction to establish best practices, particularly formal collaborations with Centers for Medicare and Medicaid Services and the Department of Veterans Affairs.

ASHP appreciates this opportunity to present its written comments on the Science and Technology Report. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at [jcoffey@ashp.org](mailto:jcoffey@ashp.org).

Sincerely,



Justine Coffey, JD, LLM  
Director, Federal Regulatory Affairs