

**American Society of Health-System Pharmacist's  
Presentation at the Food and Drug Administration's  
April 14, 2004, Public Meeting of the Drug Importation  
Task Force**



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My name is Gary Stein, and I am the Director of Federal Regulatory Affairs of the American Society of Health-System Pharmacists (ASHP). ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of health care systems. I am pleased to provide you with ASHP's views on the importation of prescription drugs into the United States.

The American Society of Health-System Pharmacists (ASHP) has a long history of advocating Congress and federal agencies about the importance of maintaining the integrity of our nation's drug distribution system.

For a more than 50 years, the US could boast the safest, most tightly regulated system for distributing prescription drugs. Today, there are challenges facing that system. A growing illegal drug trade, including counterfeit medications, rogue Internet sites, and efforts to open US markets to medications imported from abroad have all raised questions regarding the FDA's ability to respond to those challenges. In particular, the issue of the safety of the drug supply is being obscured by the issue of allowing individual citizens to purchase prescription drugs at lower prices from overseas locations.

***Impact of Unapproved Drugs:*** The scope and volume of unapproved drugs entering the United States has raised the concern of ASHP members. That is why ASHP's House of Delegates will vote this June to reaffirm the following policy:

To oppose importation of pharmaceuticals except in cases in which the Food and Drug Administration determines it would be necessary for the health and welfare of United States citizens.

There is another factor of the importation issue that has not been addressed adequately, and it relates to foreign terrorism and our nation's counter-terrorism activities. The

integrity of the drug supply and the health of consumers is at significant risk if terrorists utilize more lenient importation rules to introduce harmful agents into the United States.

•***FDA's Ability to Assure Safety:*** The FDA's regulatory system has been the world's "gold standard" of drug approval. To assure the safety of imported products, the FDA will need significantly more resources to examine those products for quality, purity, safety, and effectiveness.

•***Regulatory/Legislative Issues:*** The FDA must have the authority to assure the same level of safety for imported drugs as consumers expect from drugs purchased at a State-licensed pharmacy. There should be no added level of risk that ASHP's members would consider acceptable.

•***Technology:*** The FDA's efforts to encourage manufacturers to include track and trace technology into their product packaging for anti-counterfeiting measures should work as well to prevent the importation of unapproved or counterfeited drug products.

•***Financial Impact:*** The FDA must thoroughly study the financial impact of importation to determine whether it would actually lower the cost of drugs for American consumers. Regulations put into place to implement section 1121 of the Prescription Drug, Improvement and Modernization Act of 2003 must not be burdensome to pharmacists and wholesalers.

ASHP appreciates the opportunity to comment to the FDA on this significant issue. We are ready to assist the Department of Health and Human Services in any way in developing its policies relating to the importation of prescription drugs.