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

RE: Docket No. 2003N-0361 Anti-Counterfeit Drug Initiative

TO WHOM IT MAY CONCERN:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Food and Drug Administration's (FDA's) announcement in the August 26, 2003, *Federal Register* that the agency was establishing a docket to receive information and comments on the serious problem of counterfeit drugs entering the nation's drug supply chain and the October 2, 2003, Interim Report of the agency's Counterfeit Drug Task Force. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals (including outpatient services), health maintenance organizations, long-term care facilities, home care agencies, and other components of health systems.

In June of this year, ASHP adopted a policy on counterfeit drugs that states, in part:

To encourage the FDA to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers and manufacturers) from purchasing legend drugs from unlicensed entities and (2) to accurately document at any given point in the distribution chain the original source of drugs and chain of custody from the manufacturer to the pharmacy.

The task force's interim report addresses four topics: Regulatory and Legislative Issues, Industry and Health Professional Issues, Technology Issues, and Public Education. ASHP's comments follow accordingly.

Regulatory and Legislative Issues

Most consumers have no idea of the scope and complexity of the drug distribution chain and its business components, particularly the buying and selling of products between wholesalers. ASHP remains extremely concerned about potential vulnerabilities in the

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pharmaceutical supply chain, particularly with respect to secondary distributors. While these entities may perform a role in providing needed medications in some select situations, ASHP believes that stronger state and federal oversight are needed. Any changes to federal law and regulation should be patterned after recent legislation enacted in Florida. Florida's new law begins to address the lack of authenticating and documenting the chain of custody of a product from the originating manufacturer. This is particularly important with respect to the high-risk drugs identified by the state as being prone to counterfeiting. Recent discussions by ASHP's policy-recommending Councils noted the need for uniformity in state regulation of a national standard in order to maintain the integrity of the drug supply. However, we should be sensitive to the unintended consequence of the creation of new barriers in distributing prescription drugs, particularly with respect to legitimate returns of unused product from pharmacies.

ASHP does not believe that paper pedigrees are an optimal solution to the counterfeiting problem. However, ASHP believes that the development of a limited, uniform list of drugs considered to be at high risk for counterfeiting, determined by the FDA, should be a priority. Products on this list should not be shifted around among wholesalers. This list could be maintained through a paper system as an interim step in protecting public safety. Once electronic track-and-trace systems are more available, this interim step should be automated and expanded.

In terms of augmenting state pharmacy practice acts, ASHP believes that attempting to rely on state boards of pharmacy to improve control over wholesalers will require all states to take action similar to Florida and, therefore, will be inconsistent and potentially delayed. In the meantime, counterfeiters will simply move to states with fewer restrictions and controls. Boards of pharmacy and state health departments do not have the resources needed to effect the needed changes at the state level, and effective anti-counterfeiting measures will be slow in coming. The FDA should become more involved in monitoring wholesalers, including taking the lead in developing a national standard for tracking the distribution of drugs that can be uniformly regulated by the states.

A question that the FDA's counterfeiting task force asks in its interim report is whether there should be increased penalties for counterfeiting drugs. The report notes that "the penalties for counterfeiting drugs are substantially less than for other types of counterfeiting." Counterfeit drugs pose a serious public health threat to consumers of prescription drugs. The FDA should work with Congress on legislation that would significantly increase the penalties for counterfeiting drug products.

Industry and Health Professional Issues

Electronic means and systems for alerting pharmacists to counterfeit products already exist through professional organizations. For example, ASHP maintains an e-mail list of

over 23,000 members who receive news items from us on a weekly basis. We have already offered ASHP's services to the FDA in alerting subscribers to that list and hospital pharmacy directors about any counterfeit drug notice the agency issues. The development of a new, independent counterfeit drug alert network is not needed, since these other systems exist and the cost of populating e-mail addresses and keeping contact information current for such a system would be prohibitive. ASHP stands ready to provide rapid alerts to members and hospital pharmacy departments about counterfeit drug incidents, which is in keeping with our longstanding partnership with the FDA's MedWatch reporting system.

Pharmacists should be the focal point for patient contact, education, and follow-up (assisting patients in receiving appropriate treatment and monitoring and documenting patient outcomes) when a product is suspected of being counterfeit. Pharmacists will need to consider the possibility of counterfeiting when an unusual patient response to a drug occurs, including previously unrecognized adverse drug reactions. Training materials should also be developed to educate pharmacy and product-receiving staff with information on how to screen product packaging to detect counterfeit drugs and what steps to take when they find a suspicious product. As an initial step in developing such materials, is the attached document -- "ASHP Strategies to Protect Against Drug Counterfeiting" -- that ASHP has prepared for its members in their ongoing efforts to ensure the integrity of drugs used in U.S. health-systems. This document is available on ASHP's website at <http://www.ashp.org/practicemanager/ASHPAnti-counterfeitingStrategies.pdf>. ASHP is ready to assist the FDA in developing information on combating counterfeit drugs for health professionals in general and health-system pharmacists in particular.

Technology Issues

ASHP believes that applying technology for overt security methods will be of limited value to most pharmacists as a means of verifying the authenticity of a drug product. The reality is that most hospital pharmacies stock more than 1,500 distinct products from hundreds of vendors. It would be virtually impossible for pharmacy staff to be knowledgeable about the specific overt methods for each company and product. In addition, many experts agree that overt security methods should be changed at least annually to keep ahead of counterfeiters. All of these factors contribute to the complexity of the problem.

Covert security methods may be of some value as a means of authenticating product, but only when the product is suspect. Whatever technologies are adopted need to be practical and inexpensive for use at the pharmacy level. Funds might be better spent on technology for a universal electronic pedigree for drug products facilitated through some form of machine-readable coding on drug packaging.

Anti-counterfeiting measures should focus on track-and-trace technology. Whatever technology the FDA or drug manufacturers choose to use should be workable in today's real world situations as well as be adaptable to new and emerging technologies. Also, one of the options that the FDA's counterfeiting task force notes in its interim report is for manufacturers to "package all finished dosage form drugs in unit of use packaging as appropriate for the particular product (e.g., tablet, multi-dose vial) at the point of manufacture, as is now done in many nations." ASHP encourages the FDA to require such packaging in order to obviate the need for repackaging, which contributes to counterfeiting, as well as to benefit patient safety.

The counterfeiting task force's interim report poses questions on how anti-counterfeiting measures should be validated (Question A-10). ASHP believes that a means of authenticating a product suspected of being counterfeit is needed if future systems are to be effective. The authentication needs to occur at the pharmacy level so that pharmacies know whether they can release a product for use or whether it should be quarantined for follow-up with the FDA or other authorities. If authentication steps are too daunting and slow to provide information, busy pharmacists will be less likely to quarantine inventory and ship it off-site for authentication.

The task force also questions whether the direct shipment of products to retailers and other end users might reduce the potential for counterfeiting. ASHP believes that the wholesaler/distributor industry plays a vital role in maximizing the overall efficiency of the supply chain, resulting in lower inventory carrying costs for hospitals and improved availability through simplification of ordering and receiving. We also believe that the pharmacist plays an essential role in assuring that patients receive and utilize their medications correctly. Therefore, any system that bypasses the typical wholesale distribution process (such as a restrictive drug distribution system) or bypasses the pharmacy, would result in greater costs, reduced efficiency, and potential harm to patients.

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Public Education Issues

Public education activities should focus on overall public awareness and seriousness of the counterfeiting problem, but generally not focus on specific products and avoid causing unwarranted public panic. At the same time, such educational activities should reinforce the need for patients to adhere to their medication regimen and consult with a pharmacist if there is anything out of the ordinary about their medications. Public education activities can increase public awareness about the potential for drug counterfeiting and encourage consumers to become more proactive in identifying potential counterfeit drugs. Messages should alert patients to recognize problems such as different appearance, taste, or packaging of drugs and should instruct consumers to bring these problems to the attention of their pharmacist. Perhaps public education programs focusing on product integrity could be the focus of next year's National Pharmacy Week campaign.

ASHP appreciates the opportunity to present its comments on this important patient-safety issue to the FDA. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-657-3000 ext. 1316, or by e-mail at gstein@ashp.org

Sincerely,



Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Attachment



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ASHP Strategies to Protect Against Drug Counterfeiting

This list was developed to serve as a resource for health-system pharmacists in their ongoing efforts to ensure the integrity of drug products used in U.S. health systems. These actions should help prevent the acquisition of counterfeit drug products. Note: this list will continue to be revised as new information becomes available, so please check for updated information. Suggested additions to the list should be sent to: sections@ashp.org

Product Source:

1. Contact your primary wholesaler and inquire about their anti-counterfeiting measures and sources of product. Make sure your suppliers are taking steps to limit its sources of products to authorized manufacturers and authorized distributors.
2. Check the FDA website at least weekly for new reports of counterfeit products detected in the pharmaceutical supply chain. The FDA MedWatch website is at: <http://www.fda.gov/medwatch/SAFETY/2003/safety03.htm>. For questions about a specific product you can reach the FDA at 888-463-6332.
3. Check your group purchasing organization (GPO) website for reports of counterfeit products. Websites for the national GPOs are:

http://amerinet-gpo.com	http://medassets.com
http://broadlane.com	http://mhainc.com
http://www.consorta.com	http://www.novationco.com
http://healthtrustpg.com	http://www.premierinc.com
http://medmanagement.com/services/purchasing.asp	
4. Contact your Board of Pharmacy, Department of Health, or other appropriate state agency periodically to determine whether there are problematic wholesalers in your state. Board of Pharmacy contact information can be found at: <http://www.nabp.org>

Distributors:

5. Limit or eliminate the use of secondary distributors unless you can verify that they are an authorized distributor purchasing from authorized manufacturers and are in good standing with your State Board of Pharmacy or other licensing agency. Verify that they are in compliance with the HDMA Voluntary Guidelines for Pharmaceutical System Integrity available at <http://www.healthcaredistribution.org>

Security Measures:

6. Re-evaluate pharmacy department security measures to minimize risk of diversion or entry of counterfeit products. Consider the following:
 - monitoring access by cameras and ID readers
 - using automated supply stations where additional controls are needed
 - assuring delivery of drugs to the pharmacy directly, not to a loading dock
 - altering drug packages for products in inventory to make them less resalable (eg. mark box with hospital name, tear off box tops)
 - completely destroying empty drug packages and vials so that they may not be removed from the trash and refilled with counterfeit product
 - removing drugs from floor stock if considered at risk for diversion
 - reconciling purchasing records with billing or administration records
 - assuring that staff placing drug orders are not "receiving" inventory
 - using sequential purchase order numbers to increase accountability
 - using invoice approval as an additional verification of appropriate purchasing

High Risk Products:

7. Pay particular attention to products considered to be at 'high risk' for counterfeiting. Be mindful that expensive drug products and drugs in short supply are more likely to be counterfeited than other medications. The following list of high-risk medications was developed by the State of Florida as part of its anti-counterfeiting legislation:

Anti-retrovirals:

Combivir (lamivudine/zidovudine)	Crixivan (indinavir sulfate)
Epivir (lamivudine)	Retrovir (zidovudine)
Videx (didanosine)	Viracept (nelfinavir mesylate)
Viramune (nevirapine)	Zerit (stavudine)
Ziagen (abacavir sulfate)	Sustiva (efavirenz)
Trizivir (abacavir sulfate/lamivudine/zidovudine)	

Anti-infectives:

Diflucan (fluconazole)

Rocephin (ceftriaxone sodium)

Other high cost products:

Epogen (epoetin alfa)

Lamisil (terbinafine)

Neupogen (filgrastim)

Procrit (epoetin alfa)

Serostim (somatropin, mannalian)

Zofran (ondansetron)

Zyprexa (olanzapine)

Immune globulin (various brands)

Lupron (leuprolide acetate)

Nutropin AQ (somatropin, e-coli)

Risperdal (risperidone)

Zocor (simvastatin)

Zoladex (goserelin acetate)

Education:

8. Educate all pharmacy staff on the problem of counterfeiting, what they should look for, and how to report a suspicious product. Provide additional training and instruction to those pharmacy staff who order and/or receive products from distributors. Alert clinical and staff pharmacists to consider counterfeit product as a possible reason for an unusual adverse drug reaction or unusual response to a medication.
9. Consider how nursing, medical staff, and patients should be alerted to the potential for counterfeit products. Review policies for medication acquisition with your Pharmacy and Therapeutics Committee to assure that necessary controls are in place.

Patient Feedback or Complaints:

10. Take comments and complaints about products seriously and investigate them promptly. Many counterfeit products were discovered only after patients complained of a change in effectiveness or a change in taste of their oral medications.

Unauthenticated Product:

11. If you encounter a questionable product, contact the manufacturer and wholesaler to determine follow-up steps to verify authenticity. If the product is confirmed not to be authentic, then the FDA should be contacted through the MedWatch program (<http://www.fda.gov/medwatch/>) or at 800-332-1088.

Updated 10/6/2003