

**American Society of Health-System Pharmacists
Presentation at the Food and Drug Administration
Anti-Counterfeit Drug Initiative Workshop and
Vendor Display, February 8, 2006**



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My name is Douglas Scheckelhoff, and I am the Director of Pharmacy Practice Sections of the American Society of Health-System Pharmacists (ASHP). ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals and other components of health systems.

ASHP is pleased to provide comments in response to the FDA's notice of this workshop. We believe that adoption of RFID track-and-trace technology is vital to all our mutual concerns about counterfeit drugs entering the nation's drug supply chain. RFID shows true promise as a means of providing an electronic pedigree for more accurate documentation of the chain of custody of legitimate products from the manufacturer to the pharmacy.

I would like to start off by making one thing very clear, however. We believe that the current focus on RFID technology to track products through the supply chain is well placed. While there may be a point in the future where the use of RFID tags at the unit dose level is desirable, we believe that the first priority in hospital drug administration verification technology should remain with bar codes. Our data has shown a dramatic increase in the adoption of bedside bar code technology to improve the safe administration of medications in hospitals. The percentage of hospitals using bar code medication administration rose from 1.5% in 2002 to 9.4% last year. While we still have a way to go, this has marked a significant improvement in patient safety, and we are still two months from the full implementation of the FDA's bar-code regulations. We do not wish to send the signal that hospitals should hold off on implementing bar code technology because point of care RFID is just around the corner. In fact a great deal of work and study will need to be done before that might become a reality. Bar code technology is here now and saves lives every day.

It is noteworthy, though, that despite the clear benefit unit dose brings to patient safety, many manufacturers have chosen to stop producing unit dose packages, leaving hospitals no choice but to expand their own repackaging operations. In fact, reports have shown a 30% drop in unit dose packaging in the last five years. This has resulted in inefficiency in the U.S. healthcare system and an increased opportunity for error.

ASHP also encourages the FDA to consider the implications for hospitals as the agency contemplates actions or recommendations related to RFID technology. Much of the focus has been on the impact, be it good or bad, on chain pharmacies and the large wholesalers. ASHP believes that the U.S. hospitals and health-systems and their 10,000 points of drug distribution also have a role to play in the successful implementation of this technology.

A key role for RFID in hospitals will be to manage inventory and prevent diversion. The use of technology for inventory management has been limited to date, even though many hospitals carry a million dollars or more in inventory. The need to assure product availability while keeping the least amount on the shelf is critical and could be improved greatly with the proper use of technology such as RFID. There have been several reports of large scale diversion of high cost drugs, primarily injectables, from hospitals. The largely manual systems in place in most hospitals do little to prevent this from happening. ASHP supports the use of this type of technology to track products, tighten the system, prevent theft and losses to hospitals, and avoid another entry of adulterated products into the supply chain.

Issues raised by the FDA's *Federal Register* notice:

When RFID tags should be turned off

The issue surrounding turning off RFID tags for products used in hospitals is much different from those surrounding products dispensed from community pharmacies. In nearly all cases, the drug package, vial, or bottles discarded after a patient's dose is prepared. If the tag is not turned off, there is potential for active RFID tags being disposed of in hospital dumpsters and being readily accessible to criminals seeking empty containers for redistribution of counterfeit products. The tags must be deactivated.

Ownership and transparency of data

ASHP believes that the RFID data must be transparent to the dispensing pharmacist, no matter where the ownership of that data is determined to reside.

While there are many possible models for how supply chain data could be managed, an essential requirement for hospital pharmacy end users is that there is transparency and a paper trail back to the manufacturer. The hospital pharmacy should be able to review where products have traveled if they have been through more than just the manufacturer and initial wholesaler.

Ways to affix the RFID tags onto products

RFID tags must be affixed onto products in order to both track products and prevent diversion. Tags can be affixed on the outside of product containers, which would help track the product through the supply chain, but this does not help in thwarting drug diversion. There is value in having tags that cannot be easily removed or deactivated.

Ideally RFID tags should be affixed to products to both track products and, where possible, prevent diversion. For example, affixing the tag to the outside carton or overwrap should be minimized; although this would meet tracking needs, it would not prevent diversion if the drug vial is easily removed from the carton and the information in RFID tag is lost. This is particularly important for high-cost drugs that are prone to diversion.

Continuing the stay of the effective date of the PDMA regulations

Rather than continue the stay of the Prescription Drug Marketing Act regulations beyond the current December 1, 2006, date, the agency should set a target date by which it will require either an electronic or paper pedigree to be mandatory.

Minimum Standards for Wholesaler Licensing

The FDA asks how effective state standards are in enforcing wholesaler licensing laws and regulations. The agency also asks how a universal pedigree might alleviate concerns raised by barriers individual states place on passing a pedigree for a drug that moves from one State to another with different pedigree requirements.

The problems our members have seen are reflective of the reality and that those who intend to deceive know well where the regulations are most easily ignored. Given the national and international nature of the drug supply chain, ASHP believes that the stakes are too high to allow a fragmented regulatory framework to govern pedigree requirements. Adequate resources should be funneled into one cohesive national policy that is more likely to result in more uniform and stronger enforcement.

In conclusion, ASHP believes that a secure tracking system for drug products is an imperative at this time. The FDA has stated that adoption and widespread use of reliable track and trace technology is feasible by 2007. Nothing should stand in the way of its implementation.