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May 19, 2008

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

Re: Docket No. FDA-2008-N-0121, Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Food and Drug Administration's (FDA) request for information relating to technologies for prescription drug identification, validation, track and trace, or authentication. 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 is concerned about the current lack of interoperability of all data that identifies drug products. Radio-frequency identification (RFID) and bar-code technologies in the electronic pedigree (e-pedigree) process should be usable within the systems to which they belong. Barcode point-of-care systems, pharmacy robotics, pharmacy packagers, re-packagers, and other automated compounding devices must be able to utilize the identifiers determined for e-pedigree. This usability will allow for enhanced patient safety since there will be one universal identifier agreed upon by all involved in the medication use process.

Currently, ASHP members are struggling with inconsistencies relating to the National Drug Code (NDC) and its application to barcode point-of-care, clinical information systems, and hospital financial systems. ASHP would like to discuss opportunities for collaboration with the FDA regarding the standardization and usability of the NDC and/or other alternative drug identification systems.

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ASHP appreciates the agency's willingness to solicit information from various stakeholders concerning technologies for prescription drug identification, validation, track and trace, or authentication. The ASHP Section of Pharmacy Informatics and Technology provided significant input into this response.

ASHP believes that Radio Frequency Identification (RFID) could be used where barcodes are currently in place, including patient identification and medication identification. Medications are identified at many points in the provision of health care, including inventory acceptance and control, loading and unloading from automation, and medication-patient identification for bedside barcode medication administration.

For automatic tracking, encryption should be used in any portion of the supply chain that could be compromised by an outside source. For example, encryption should be used in the event someone submits an unauthorized order transmittal or RFID to provide inaccurate information to facilitate the diversion of a controlled substance. Based on the nature of prescription drugs, it would be beneficial to encrypt all prescription drug-related communications.

EPCglobal's Electronic Pedigree Document specification for serializing products in compliance with pedigree regulations in the United States contain standards that are necessary for supply chain use of the specific technology. The EPCglobal standard includes an e-Pedigree document schema as well as an e-Pedigree envelope schema that companies can use as a way to hold multiple e-Pedigrees together in a single document for electronic transmission. In the United States, while these standards are established, their use within industry is uncertain since e-pedigree laws in some states have not yet gone into effect.

ASHP appreciates this opportunity to present its written comments on FDA's request for information. 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.

Sincerely,



Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs