

NABP Plays a Role in FDA's RFID Conference

During a panel discussion at Food and Drug Administration's (FDA) Counterfeit Drug Task Force Public Workshop in Bethesda, MD, February 8-9, 2006, NABP offered its viewpoints on radiofrequency identification (RFID), or track and trace technology, in terms of curbing counterfeit medications. The meeting was held to discuss the December 1, 2006 expiration of the Prescription Drug Marketing Act (PDMA) of 1987's pedigree stay.

The implementation of RFID and track and trace technologies enables the creation of a pedigree for medications recording distribution of drugs from the manufacturer through the acquisition and sale by any wholesale distributor or repackager down to the pharmacy level.

According to NABP Executive Director/Secretary Carmen A. Catizone, "NABP believes that implementation of a track and trace technology system by 2007 is possible and will secure the medication distribution supply chain through the creation of an electronic pedigree and other enhancements."

Catizone further explained that this optimism is based upon two developments. First, the necessary framework to license and regulate wholesale

distributors and establish an appropriate environment for the implementation of track and trace technologies is in the process of being implemented by the states. Legislation and regulation has been adopted or is under consideration in the following states: Arizona, California, Florida, Indiana, Iowa, Nevada, New Jersey, New Mexico, Oklahoma, Texas, and Virginia. For example, by July 1, 2006, all medications in Florida must have a pedigree in either a paper format or an electronic format. Secondly, pilot projects for track and trace technologies have demonstrated that such concepts can be developed and implemented successfully by the 2007 deadline.

Catizone told the panel that several areas must be addressed in order to achieve the desired and realistic goal of implementing some degree of track and trace technologies by 2007.

It is critical that industry standards and a common information technology infrastructure be established so medicines can be tracked across the entire supply chain. Before RFID can be widely used throughout the pharmaceutical industry, compatible technologies must be developed and coding standards created. It is imperative that the wholesale industry work

with all of the components that affect the distribution chain to develop universal standards for the design and implementation of the track and trace technologies. Without uniform standards and compatible design for the various technologies, the resulting system will be nonfunctional and cost prohibitive. The existence of multiple variations of systems will also complicate all facets of the wholesale distribution supply chain and essentially negate the desired outcome of accounting for products throughout the medication distribution supply chain.

Catizone noted that it is important for FDA to continue to expand its leadership role concerning the use of the track and trace technology. To date, FDA's efforts have largely been to encourage a voluntary approach toward widespread adoption of electronic track and trace technology. NABP believes this voluntary approach may not be enough, particularly noting the slow progress of RFID and electronic pedigree. NABP encourages FDA to change its approach from voluntary to mandatory, and, in key areas to be identified by FDA and the states, mandate necessary components and standards.

In FDA's May 18, 2005 report *Combating Counterfeit Drugs: A Report of the Food*

and Drug Administration Annual Report (Report), it was stated "... adoption and wide-spread use of reliable track and trace technology is feasible by 2007. . . . Implementation of RFID will allow supply chain stakeholders to track the chain of custody (or pedigree) of every package of medication."

The *Report* further states that FDA has undertaken the development of standards for track and trace technology; this will ensure that the electronic track and trace technologies that are adopted are comprehensible and data communication systems are interoperable.

In response to questions regarding RFID and regulatory issues, FDA issued a Compliance Policy Guide (CPG) for implementing RFID feasibility studies and pilot programs as an important and essential step in moving this technology forward. The CPG outlines FDA's current beliefs regarding several labeling, current Good Manufacturing Practices, and other regulatory issues that may arise by affixing an RFID tag to a drug product for a feasibility study or pilot program.

In November 2004, FDA created the RFID Workgroup, which is charged to monitor the

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June 2006 FPGEE Administration Approaching

NABP announces that the next Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) administration is scheduled for June 24, 2006, in three United States locations: San Mateo (San Francisco), CA; Northlake (Chicago), IL; and New York, NY.

The FPGEE is one requirement of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program, which NABP provides as a means of documenting the educational equivalency of an applicant's foreign pharmacy education, as well as his or her license and/or registration. During the FPGEC Certification process, applicants are required to submit certain documents or have the documents submitted to NABP from educational or

licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants are also required to pass the FPGEE, the Test of English as a Foreign Language™ (TOEFL®), and the Test of Spoken English™ (TSE®). Applicants who have passed the FPGEE but have not satisfied the language requirements for the portion required for the FPGEC Certificate need to be aware that the TOEFL and TSE will be phased out in 2006 and replaced with the TOEFL Internet-based Testing (iBT), an online version of the TOEFL. During the phase-out period of the TOEFL and TSE and the phase in of the TOEFL iBT, either minimally acceptable TOEFL iBT scores or a combination of minimally

acceptable TOEFL and TSE scores will satisfy the language requirements for the FPGEC Certificate.

The FPGEC Certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 jurisdictions that recognize the certification. NABP continuously alerts applicants that the FPGEC Certificate is not a license to practice pharmacy. Applicants who receive the FPGEC Certificate are qualified by the state boards of pharmacy that accept the FPGEC Certificate to continue the licensure process and take the North American Pharmacist Licensure Examination™ and other required examinations in those jurisdictions that accept this certification. To date, 50 state boards of pharmacy

recognize the FPGEC Certificate.

Beginning in April 2006, NABP partnered with Educational Credential Evaluators, Inc for the educational credential evaluation of applicants to the FPGEC Certification Program. This change to the processing of FPGEC Certification applications was made in response to a continuous increase in applications for the FPGEC Certification Program and NABP's ongoing efforts to improve processing times.

Applicants with questions about the FPGEC Certification Program, the FPGEE, or Pre-FPGEE® – the practice examination for the FPGEE – may visit NABP's Web site at www.nabp.net for more information or to request FPGEC Certification Program applications. ☎

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adoption of RFID in the pharmaceutical supply chain, pro-actively identify regulatory issues raised by track and trace technology, and develop straightforward processes for handling those issues. According to FDA, "... the workgroup will improve communication with members of the supply chain on RFID related issues and will facilitate both the performance of pilot studies

and the collection of data needed to formulate policy."

According to the *Report*, FDA's next steps regarding track and trace technology include:

1. Continue to play an active role in public and private sector efforts toward developing an "electronic safety net" for the drug supply, including the adoption and widespread use of

reliable track and trace technology in 2007.

2. Continue to facilitate and monitor activities to establish standards for numbering systems, chip frequency, electronic pedigree, and data-sharing and security.
3. Continue to encourage and foster research on the use and potential impact of RFID on drug and biological products.

4. Regularly review the extent and pace at which RFID is being adopted.

NABP will continue to work closely with FDA to ensure that RFID technology is implemented to curb counterfeit medications and protect patients' safety. Also, the results of the findings from FDA's panel discussion in February are expected to be released sometime in May 2006. Results from this meeting will be highlighted in a future NABP *Newsletter*. ☎