



FDA, Counterfeit, and RFID Technology

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APICS members should note the implications of an article that appeared in the *Wall Street Journal* on February 19, 2004. Among other things, the article makes mention of a report recently released by the FDA on the future role of RFID technology in the prevention of counterfeit medicines. Below is a brief summary of the WSJ article.

“FDA Plans Bogus-Drug Crackdown”

Use of Electronic Tracking Will Help Protect Medicines; Difficulty Unraveling Origins

By ANNA WILDE MATHEWS

- The FDA will focus on technologies that allow track and trace of medicines.

- No immediate solution for track and trace has been proposed.

- The FDA has established a broad goal of implementing RFID technology by 2007.

This development has implications for all industries. Both Wal-Mart and the Department of Defense have announced adoption of RFID standards within the last year. It appears that momentum is gaining concerning the application of Auto-ID technology in practice. There are additional projects currently under consideration by other government organizations concerning the application of track and trace technology using RFID.

A copy of the FDA report can be found at:

http://www.governmentguide.com/govsite.adp?bread=*Main&url=http%3A//www.governmentguide.com/ams/clickThruRedirect.adp%3F55076483%2C16920155%2Chttp%3A//www.fda.gov

Besides the application of RFID technology, the FDA report also mentions other initiatives designed to decrease the chances of counterfeit drugs entering the U.S. pharmaceutical supply chain. Alone, RFID technology is not the total solution to combating counterfeit drugs.

As background information, interested APICS members can download a copy of our initial research on “Securing the Pharmaceutical Supply Chain” that was released to the public in September 2003 at:

<http://ed-w.info/MIT-AUTOID-WH021.pdf>

This is a non-commercial web site. Other articles on Auto-ID can also be found through the web directory at www.ed-w.info my personal web site.

Attached at the end of this article is an appended version of the FDA report dealing with the implementation plan for RFID in the pharmaceutical supply chain. I have highlighted in blue sections that are significant. Among important points to consider:

-- The FDA initiative calls for tagging cases as a first step, with plans to tag pallets and then packages.

-- Before wide-spread application of RFID, testing must occur concerning the impact of electromagnetic fields on the stability of drugs. Increasingly, pharmaceutical products are becoming highly bioengineered molecules that are inherently unstable in nature. Though the chances are low, additional energy transmitted from readers might break critical chemical bonds. Though there is no direct evidence that the levels of energy associated with RFID are high enough to cause product quality problems, testing must take place to provide empirical evidence for conclusive proof.

-- In the report, the FDA makes the statement, “Use of mass serialization to uniquely identify all drug products intended for use in the United States is the single most powerful tool available to secure the U. S. drug supply.”

-- As part of the report, the FDA has published a timeline for adoption of RFID technology.

-- It appears the FDA is proposing the use of two different frequencies for RFID.

In a separate development, APICS has agreed to create a discussion list totally dedicated to Auto-ID technologies. An announcement concerning the list will happen soon. I believe the list will be restricted to APICS members only. I will continue to contribute to the new list, sharing what I know about developments in the field. The price of joining APICS is small in relation to the information that you will gain from being part of

this list. I believe that APICS members can make significant contributions to the development of Auto-ID technology through discussions about interface issues with existing ERP systems.

Finally, within the next two weeks I will be releasing a comprehensive research report on managing the large amounts of data that will be generated from Auto-ID technology. In many respects, this research is “Auto-ID, Part II.” I am working with David Brock, Principle Research Scientist at MIT, along with others on this important project. In advance, I welcome any constructive comments from APICS members concerning this applied research.

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Select Excerpts From the FDA Web Site:

http://www.governmentguide.com/govsite.adp?bread=*Main&url=http%3A//www.governmentguide.com/ams/clickThruRedirect.adp%3F55076483%2C16920155%2Chttp%3A//www.fda.gov

COMBATING COUNTERFEIT DRUGS A Report of the Food and Drug Administration

February 2004

e. Radio-frequency Identification (RFID) Technology

1) What FDA sought comment on:

- Whether a pedigree for all drug products can be achieved by phasing in track and trace technology (i.e., electronic pedigree) starting at a case and pallet level for products likely to be counterfeited and progressively including all products at the case, pallet, and package level; and
- Whether, as an interim measure, prior to widespread adoption of track and trace technology all drugs and biologics likely to be counterfeited should be tracked and traced either by limiting the number of transactions of the product or by using available track and trace technology, identifying the drug at the case and pallet level, and preferably at the product level, throughout the distribution system.

2) What the comments said:

There was [universal support](#) for the adoption of electronic track and trace technology. RFID was cited as being the technology with the strongest potential for securing the supply chain but that it was not ready for widespread commercial use with pharmaceutical products. Many costs, potential benefits, and unresolved issues related to RFID were cited. The potential benefits included the ability to control inventory and conduct rapid, efficient recalls, while costs that could hinder the adoption of RFID included purchase of tags and other hardware, integration into existing information systems, and compliance with regulatory requirements (e.g., labeling, electronic records). Important unresolved issues included the need to develop standards and business rules for RFID, the need to address database management issues, and the need to [determine the effect of RFID on product quality](#).

FDA was also informed that some companies are planning feasibility studies concerning business uses of RFID for early this year and that other activities related to creating standards, business rules, and migratory pathways for RFID are also ongoing. A detailed discussion of these activities and other comments concerning RFID is in Appendix B.

3) Discussion

[Use of mass serialization to uniquely identify all drug products intended for use in the United States is the single most powerful tool available to secure the U. S. drug supply.](#) Mass serialization involves assigning a unique number (the electronic product code or EPC) to each pallet, case, and package of drugs and then using that number to record information about all transactions involving the product, thus providing an electronic pedigree from the point of manufacture to the point of dispensing. This unique number would allow each drug purchaser to immediately determine a drug's authenticity, where it was intended for sale, and whether it was previously dispensed.

Although there is general agreement that widespread use of mass serialization is inevitable, several important issues remain unresolved, including the migratory path(s) that participants in the drug distribution system will follow as they begin to serialize their products, and the most likely timeline for widespread commercial use.

[It currently appears that the technology most likely to bring mass serialization into widespread commercial use by the pharmaceutical industry is RFID, although two-dimensional bar codes may be used for some products.](#) RFID technology includes not only the silicon tags containing the EPC, but also antennas, tag readers, and information systems that allow all users to identify each package of drugs and its associated data. This data can be used not only to authenticate drugs but also to manage inventory, conduct rapid, targeted recalls, prevent diversion, and ensure correct dispensing of prescriptions.

[Acquiring and integrating RFID technology into current manufacturing, distribution, and retailing processes will require considerable planning, experience, and investment of resources.](#) Currently, some manufacturers, wholesalers, and retailers are developing business plans and testing mass serialization using RFID while others are taking a wait and see approach. Due to rapid technologic advancements, the lack of significant market place

experience with it in the pharmaceutical supply chain, each participant is best situated to determine his optimal path(s) to adopting it.

Therefore, FDA has identified near term actions, described below, for it to take in order to facilitate the performance of mass serialization feasibility studies using RFID, and to assist stakeholders as they migrate towards the use of RFID technology.

In the long term, after there is significant market place experience with RFID, FDA plans to propose or clarify, as necessary and appropriate, policies and regulatory requirements relating to the use of RFID. Labeling, electronic records, product quality, and Current Good Manufacturing Practices (cGMP) requirements are issues that have arisen in connection with RFID. However, regulatory or policy determinations regarding these, or other, issues should not be made until they can be informed by sufficient data and significant marketplace experience with RFID. FDA has also identified a series of actions, discussed below, that would help industry stakeholders and standard-setting organizations achieve this goal.

Lastly, stakeholders will need to ensure that they comply with the patient privacy protections provided by the Health Insurance Portability and Accountability Act as they implement use of RFID technology.

4) FDA Conclusions:

The adoption and common use of RFID as the standard track and trace technology, which is feasible in 2007, would provide better protection.

Due to industry's current initiatives, mass serialization and RFID technology is likely to be adopted according to the following timeline:

January - December 2004

Performance of mass serialization feasibility studies using RFID on pallets, cases, and packages of pharmaceuticals;

January - December 2005

Mass serialization of some pallets and cases of pharmaceuticals likely to be counterfeited;

Mass serialization of some packages of pharmaceuticals likely to be counterfeited; and

Acquisition and use of RFID technology (i.e., ability to read and use the information contained in RFID tags and the associated database) by some manufacturers, large wholesalers, some large chain drug stores, and some hospitals.

January - December 2006

Mass serialization of most pallets and cases of pharmaceuticals likely to be counterfeited and some pallets and cases of other pharmaceuticals;

Mass serialization of most packages of pharmaceuticals likely to be

counterfeited; and

Acquisition and use of RFID technology (i.e., ability to read and use the information contained in RFID tags and the associated database) by most manufacturers, most wholesalers, most chain drug stores, most hospitals, and some small retailers.

January - December 2007

Mass serialization of all pallets and cases of pharmaceuticals;

Mass serialization of most packages of pharmaceuticals; and

Acquisition and use of RFID technology (i.e., ability to read and use the information contained in RFID tags and the associated database) by all manufacturers, all wholesalers, all chain drug stores, all hospitals, and most small retailers.

FDA plans to assist, to the extent necessary and appropriate, in facilitating the rapid, widespread adoption of RFID in the drug distribution system by working with stakeholders in the following areas:

- Addressing any regulatory and policy issues related to the performance of feasibility studies;
- Addressing any regulatory and policy issues relating to the notification requirements associated with implementation of RFID;
- Addressing any product quality concerns and data issues related to the performance of feasibility studies;
- Reviewing protocols for feasibility studies;
- Working with other governmental agencies to coordinate activities;
- Encouraging stakeholders to convene meetings of supply chain participants to identify, discuss, and propose solutions to technical, business, and policy issues related to the use of RFID technology in the pharmaceutical distribution system; and
- Exploring the need for any other processes and venues that might be needed to assist stakeholders as they migrate towards the use of RFID technology.

FDA intends to regularly review the pace at which RFID is being adopted in the U.S. drug distribution system;

FDA plans to publish or clarify, as appropriate, regulatory requirements, policy guidance, and product quality testing requirements related to the use of RFID after sufficient data and marketplace experience with RFID are available to adequately inform our decision-making; and

FDA intends to consider taking further steps to facilitate the adoption of mass serialization.

1. Business steps for industry

Each industry stakeholder interested in implementing RFID would benefit from the following steps:

- Create an internal team focused on the adoption of mass serialization and use of RFID technology;
- Perform internal feasibility studies to gain experience with mass serialization and RFID technology and to identify internal business issues requiring resolution;
- Perform external pilot studies with stakeholders across the supply chain to gain experience using mass serialization and RFID and to identify opportunities, barriers and external business issues associated with them;
- Develop policy and a business case for the use of mass serialization and RFID;
- Cooperate and work with other stakeholders and government agencies to develop infrastructure and information systems to use with mass serialization of pallets, cases, and packages of drugs;
- Participate on standard setting groups developing technical standards and business rules for use of mass serialization and RFID;
- Work with government agencies and other members of the supply chain to identify and address regulatory and economic issues that could delay the adoption of mass serialization and RFID; and
- Educate other members of the supply chain and government agencies about mass serialization and RFID.

To the extent possible, it would be most useful for interested firms to perform these actions concurrently. For example, standards development requires knowledge gained from feasibility studies in order to move forward, and vice versa.

2. Standards Setting Issues

Any effort to develop standards for mass serialization of pallets, cases, and packages would be most effective if it addressed the following issues:

- [Minimum Information Requirements for the serial number -- in the case of RFID tags this means containing a mass serialization code that uniquely identifies the object to which it is attached \(e. g., minimum of 96 bits of information\);](#)
- Communication protocol standards -- in the case of RFID this means standard protocols for interrogating and reading tags;
- Reader Requirements -- Readers of mass serialization codes should be interoperable (e. g., readers must use protocols that allow them to read multiple classes of tags or bar codes, as applicable) and should be able to automatically upgrade software over an information network;
- Pedigree requirements -- this means that databases containing transaction information should be compatible (e.g., format, mark-up language);
- Information Network Requirements

1. Database Structure (e .g., centralized vs. distributive)

2. Data ownership
3. Data access (to meet business, track and trace, and recall needs)
4. Data Access controls to assure information security;
 - Software Requirements -- all applications should be compatible and compliant to assure global interoperability; and
 - Best use of Frequencies -- (e. g., 13.56 megahertz on packages and 915 megahertz on cases and pallets due to interference and read range issues).

APPENDIX B: EXPANDED DESCRIPTION OF COMMENTS RECEIVED

Radiofrequency Identification Technology

We received a large amount of information on the benefits, costs, and unresolved issues relating to RFID. These include:

Benefits

- Ability to deter and detect counterfeit drugs;
- Ability to conduct efficient targeted recalls;
- Ability to manage inventory;
- Ability to identify theft;
- Ability to identify diverted drugs; and
- Improvement in patient safety by assuring correct dispensing of drugs.

Costs

- Purchasing hardware (e.g., tags, readers) and software;
- Integration into legacy information systems;
- Database creation, security, and maintenance;
- Integration of RFID technology into existing manufacturing processes, distribution procedures;
- Compliance with regulatory requirements (e.g., cGMP, notification, product integrity); and
- Feasibility studies.

Unresolved Issues

- Need for all stakeholders to embrace the technology in similar timeframes in order to realize the full potential of RFID technology including provision of a universal electronic pedigree;
- Need to develop standards and business rules;
- Need to address database issues such as structure (e.g., central vs. distributive), ownership, access, and security;
- Clarification of regulatory requirements pertaining to use of RFID (e.g., cGMP, electronic records, notification); and

- Need for a flexible migration path to the use of RFID in order to meet the needs of different stakeholders.

Stakeholder Activities

We have been informed of several feasibility studies, starting in early 2004, that should give members of the supply chain experience using RFID as well as provide them with an opportunity to test its business uses and identify potential barriers to its acceptance. These studies include:

- Wal-Mart: drug manufacturers and wholesalers will attach RFID tags to all bottles of controlled substances;
- Accenture: coordinating a study of RFID involving manufacturers, wholesalers, and retailers that will explore the use of RFID for tracking, tracing, recalls and theft of selected pharmaceuticals;
- CVS: is studying the potential benefits that tagging and tracing pharmaceuticals and prescriptions in a retail pharmacy would have on operating efficiency, quality of patient care, and customer service; and
- Other feasibility studies using RFID are being planned in Europe to study the use of serialization for authentication at the point of dispensing.

In addition to feasibility studies, we understand that several groups representing many supply chain participants have been meeting to discuss ways to facilitate the adoption of RFID. For example the Product Safety Task Force (PSTF) convened under the auspices of the Healthcare Distribution Management Association (HDMA) is developing business requirements and identifying business issues relating to RFID technology.

The PSTF and other stakeholders have informed us that the migratory path (or phase in) to widespread use of RFID at a package level could vary by stakeholder based on the place of that stakeholder in the supply chain (e.g., manufacturer vs. retailer) and on specific costs and benefits accruing to that stakeholder (e.g., types of products manufactured, number of distribution centers, technology cost per product).

Several migratory paths were mentioned, including:

- Phasing in use of RFID technology with use at the case and pallet preceding use at the package level;
- Phasing in use of RFID technology starting with use on pallets, cases, and packages of "high risk" products with gradual inclusion of other products at all levels; and
- Use of RFID technology at the pallet and case level coupled with use of 2-D Bar Codes at the package level with gradual phase in of RFID technology at the package level.

According to stakeholders, these paths are not mutually exclusive and it is likely all of these, and other, paths will be utilized as RFID technology becomes more widely adopted.

