



# HDMA EPC

PROTECTING SAFETY AND IMPROVING EFFICIENCIES  
IN THE HEALTH CARE SUPPLY CHAIN -

## USING ELECTRONIC PRODUCT CODES

*A WHITE PAPER SUBMITTED BY*

THE HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION'S  
(HDMA) COLLABORATIVE COMMERCE COMMITTEE

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WRITTEN BY







## INTRODUCTION

The pace of commerce is not only accelerating, our world is becoming a smaller and more volatile place. Both factors exert pressure on the pharmaceutical supply chain to improve its security and its efficiency. Clearly, the business practices of the past few decades cannot cope with today's emerging concerns. Supply chain constituents are keenly aware of these changes, as are federal and state governments. While no one doubts the need to improve supply chain safety and efficiency, what is needed is a consensus on a single solution.

A true solution will improve safety and efficiency without overburdening any of our constituents. Although change usually expends both time and money, in this case, finding the right solution will streamline and improve practices and procedures, eliminating costs that have traditionally wasted human resources and time. In the end, those who bear the expense of investing in the solution should reap cost-saving benefits brought about by it.

We, the HDMA's Collaborative Commerce Committee, have been generally charged with exploring ideas that will streamline and improve collaborative commerce's best practices, processes, and technologies. More specifically, the committee is now focusing on ways to increase safety and efficiency at all levels within the supply chain and the arenas it serves. This white paper grows out of that charge. In the process of investigating solutions, we, the committee, considered these issues:

- Medication dispensing and administration errors
- Counterfeiting and product adulteration
- Legislative initiatives, such as the Georgia Returned Goods Act, importation/re-importation, and Florida pedigree
- The growing number of products with special handling or storage needs
- Product recalls
- Cost concerns
- Increasing the efficiencies within the supply chain
- A true solution must embrace an open-systems concept, giving members options that meet their needs while still fitting in an overall industry framework

Keeping in mind these criteria, the committee has worked in partnership with the Massachusetts Institute of Technology's Auto-ID Center. Founded in 1999, the Auto-ID Center is a unique partnership of almost 100 global companies and five of the world's leading research universities: the Massachusetts Institute of Technology in the US; the University of Cambridge in the UK; the University of Adelaide in Australia; Keio University in Japan; and the University of St. Gallen in Switzerland. This consortium is in charge of designing and researching a global infrastructure - a layer on top of the Internet, allowing products to be identified and tracked at any point along the supply chain.



## RECOMMENDATION

*Note: In May 2003, the Uniform Code Council (UCC) and EAN International (European Article Numbering) announced they would introduce EPCglobal, the global standards organization of the EPC network. A not-for-profit organization, EPCglobal will develop and oversee the commercialization of the Electronic Product Code (EPC)<sup>TM</sup> Network, including establishing technical standards. The industry regards this event as good news, speculating that based on UCC and EAN's reputation, the organization will most likely pursue with vigor the task of furthering the technology's transition from the lab to the real world.*

Based on the committee's work with the Auto-ID Center since October 2002, we, the committee, have concluded that the combination of a **Radio Frequency Identification (RFID)** system and a unique numbering system that delivers mass serialization offers the power and practicality to meet the needs of the healthcare supply chain. This white paper explains the factors that led us to this conclusion.

The committee realizes that implementing a new technology within the supply chain will take time, and most likely, the technology will be introduced in phases. This paper addresses the advantages of a fully implemented **Electronic Product Code (EPC)** Network, with all parties in the chain reading and recording the information that the system delivers. While the committee understands that all of these benefits will not be attained immediately, the paper presents the capabilities of the mature technology - as it will *ultimately* operate. That time is not too distant. A case in point: it is being reported that Wal-Mart is already asking its top 100 suppliers for pallet and case identification by early 2005. Wal-Mart's mandate will hasten standards development, which may mean that unit identification may be only another year or two further away.

## BACKGROUND

### THE BAR CODE

#### *Paving the way for more advanced technology*

Twenty-five years ago, the creators of bar code technology envisioned that the bar code would evolve and eventually give way to a new standard. Two-and-a-half decades later, the needs of the supply chain have grown more complex, and the need for a new standard is very near on the horizon.

In this Information Age, the need for greater product detail, faster, easier "reads," and fewer errors are rendering bar code technology in all its forms inadequate in meeting the increasing demands of the 21st century. The symbologies that began as **National Drug Code (NDC)** numbers and evolved into **Universal Product Codes (UPC)** simply cannot store the amount of detail needed.

#### *The supply chain needs a system that can identify individual product units.*

This is a critical need, the lynchpin solution that solves myriad safety and material management problems. For example -

- To be able to track and trace individual units enables the supply chain to react quickly and surely to avert threats to the nation's drug supply.
- Identifying single units protects patient safety when routinely dispensing medications in pharmacies and hospitals.
- Item-level identification simplifies inventory management at all levels within the supply chain: from moving product through the chain, to more widespread efficiencies, such as expediting recalls, improving forecasting, reducing shrinkage, and simplifying contract administration to name a few.

Using traditional bar codes is not an efficient way to meet the need of single-unit identification. Traditional bar code technology is time-consuming and labor-intensive. In a shipment of 6 cases of 12 vials each, every vial must be scanned. Moreover, scanning item-by-item invites errors - vials can be missed or scanned twice. Lastly, the bar code is a line-of-sight technology, which means that the codes can be read only when the item is positioned toward the scanner and nothing hinders the scanner's view. Many of us have witnessed this drawback as a grocery checker repeatedly scans a bag of frozen food in which the wrinkled UPC code is further obliterated by a layer of frost. Repeated scanings often come to no avail, and the checker keys in the item. While **Reduced Space Symbology (RSS)** bar codes address the issue of holding more information in a smaller space, they still require line-of-sight and item-by-item scanning. Note: the UCC and EAN recommend that

companies currently considering Reduced Space Symbology should implement it now to gain the benefit for unit-dose packaging. As EPC is introduced, it will complement the symbologies currently in use, including UPC, RSS, and UCC/EAN-128.

Today's marketplace needs more. More information. Greater efficiency. More flexibility. Easier use. The modern pharmaceutical arena is looking for ways to develop "smart products" that will talk to us, giving us detailed product information. With such information, we can connect the entire supply chain - from manufacturer to consumer, and all of the links in between.

Massachusetts Institute of Technology's (MIT) Auto-ID Center has lead the effort to design a standardized system to identify products using **RFID** tags. The tags will be embedded into products so that the product can "talk" to tag readers that items encounter all along the supply route. Tags can be attached to pallets, cases, and individual units, enabling readers to "see" the contents of entire cases and pallets at a glance. Readers at all stages of the supply chain can obtain the information needed to check-in and ship products as they work their way toward the consumer.

### **AUTO-ID TECHNOLOGY DEFINED**

*Auto-ID technology* (Automated Identification) is a general term that refers to any technology that helps tag readers identify objects. Often used in a process that automatically captures product data, Auto-ID technology identifies items, captures details about them, and transfers the data into a computer system. All is done automatically, without employees keying in the information. The goal of Auto-ID technology is to improve efficiency, reduce data entry errors, and relieve employees of tedium, freeing them to work at higher levels to further the company's goals.

Some examples of Auto-ID technologies are bar codes, smart cards, voice recognition, optical character recognition, electromagnetic identification (EMID), and radio frequency identification (RFID).

### **ABOUT RFID TECHNOLOGY**

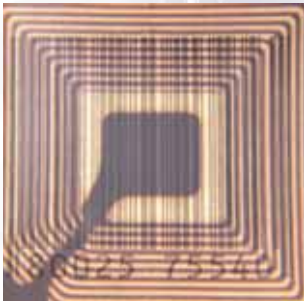
*RFID technology*, a form of Auto-ID, identifies objects using radio waves. The RFID application best suited to the supply chain works by storing a serial number on a microchip smaller than a grain of sand. Embedded on this tiny chip is an **Electronic Product Code**, an EPC™. The code on the chip identifies the product in varying degrees of detail. An antenna is attached to the chip, and together, the chip and its antenna are called a *transponder* - in everyday lexicon, they're known as *the tag*.

The tag's antenna transmits the product identification information. The information is detected by a reader, which is also equipped with an antenna. Readers can be hand-held or installed in the environment, positioned on shelves, floors, or doors. The tag and the reader exchange radio waves, and the reader then transfers the item information to computers, using a language that computers "understand."

An item's EPC is different from all other identical stock-keeping units. The EPC is similar to an item's Social Security number. In a case of 24 bottles of PseudoRx, each has a different EPC, even though they may all be Pseudo-Rx, low-dose, 81 mg, 50-count.

An EPC tag contains four pieces of information:

1. *Header*: the EPC version number
2. *EPC Manager*: the manufacturer
3. *Object Class*: the type of product
4. *Serial Number*: a number unlike any other item number



*RFID tag with barcode*

*Tags can be active or passive.* Lower in cost, passive tags have no power - they are simply read, answering the call of the reader. Active tags are internally powered, they have memory, and their data can be modified. Tags enable an item to be identified, counted, and tracked by readers throughout the supply chain. Tags can be added to items, cases, and pallets, and each tag carries information that relates to its identity. Pallets carry larger tags that can be read from farther away and supply more information than case- and unit-level tags. Tags define product pedigree, relating items to cases and lot numbers, cases to pallets, and pallets to warehouses.

*A word about performance:* In a recent demonstration, a flatbed reader "read" EPC tags on rolls of film hanging from a rack. The reader "read" 200 tags per second with 100% accuracy. Hollister Inc. reports that using an RFID system has lowered distribution costs 6% and labor costs 9% at its Tennessee plant. Says Craig Hourigan, Manager of Supply-Chain Logistics for Hollister, "The system has increased the efficiency of every aspect of the material handling process by virtually eliminating manual data entry, [and] time spent looking for product . . . . Improvements in receiving, putaway, and replenishment have reduced shippable backlog by 40%"<sup>1</sup>

## AN EPC APPLICATION

### THE SYSTEM

*Step-by-step:* Let's follow a case of Acme's PseudoRx through the supply chain. (See Diagram #1). Keep in mind that this is an oversimplified explanation of the process used to illustrate a broad view of the system. In reality, the system will handle much more complex supply paths. Moreover, the illustration assumes that supply chain members have agreed to a level of visibility of the data.

- A. The chemical plant places raw materials in drums, each uniquely numbered and tagged.
- B. The drums are shipped to Acme, the manufacturer, who then combines the raw materials to make PseudoRx. As the manufacturer fills bottles with PseudoRx, tags containing the manufacturer's pedigree are affixed to the bottles.
- C. The bottles are then staged to ship to the wholesaler.

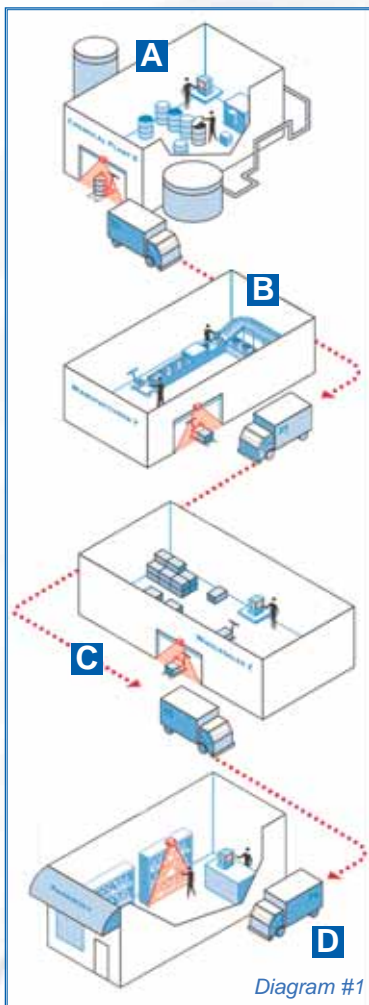
The wholesaler receives the order, breaks up the quantities of PseudoRx to fill retail orders, and begins to distribute PseudoRx to various retailers. D. These retailers can track the movement of the product from its inception to the moment it arrives in the store. When PseudoRx is purchased and leaves the shelf, the technology will tell the retailer this, too.

*Now let's examine how the technology works.*

The case of PseudoRx gets loaded onto a pallet in the manufacturing plant. As the pallet moves out of the loading dock, a reader positioned atop the loading dock door activates the smart tags on the bottles, one at a time, by bouncing radio waves on the EPC tags.

The reader sends the information to a computer system that runs a software program, called Savant. The Savant system counts and identifies the bottles of PseudoRx that are going out the door in this shipment, acting as a clearinghouse that translates data and hands it over to the **Object Naming Service (ONS)**.

The ONS server matches the EPC number on the tag to an "address" on the Internet where information about a product is stored. The address maintains extensive information about the item. While the EPC tag itself acts only as a "license plate," the serial number on the tag unlocks an infinite amount of data stored at the item's Internet address. This data can be read by Savant systems with appropriate access around the world.



<sup>1</sup> *Global Logistics & Supply Chain Strategies*, November 2002.

Because the ONS system can identify the reader that introduced the item into the system, the ONS knows which plant manufactured the PseudoRx. In the event of defect or tampering, this information could track and trace the item and easily recall specific bottles.

The ONS system then uses a language based on XML, (eXtensible Markup Language), called PML (Physical Markup Language). PML stores comprehensive data about the item - and does even more. PML enables computers to gather information and act on it. To clarify the point: a PML file will include the basics - product's name and its broad product category, when and where the product was made, its expiration date, its current location, and its temperature (if relevant). The PML file could also contain instructions for shipping the pallet to its destination, or instructions for a point-of-sale display to lower the price of an item as it nears its expiration date, or instruction for use. *See diagram, Appendix A, for more about how the system works.*

Industry has used RFID systems since World War II. Today, RFID systems authenticate a variety of products: bank cards, consumer goods, biometric devices, hospital patients, medical devices, and anti-theft devices. However, until now, the technology's expense has made it impractical for many commercial uses. What was needed was a "cheap chip." Such a chip has been developed: it is economical enough to be widely accepted. The prediction is that chips will cost less than 5¢, and readers will cost under \$200. Procter & Gamble's CIO, Stephen David, made the point at InformationWeek's 2003 spring conference: it's a small price for a manufacturer to pay to protect a \$10,000 bottle of 1,000 pills.

## INVESTMENT EFFICIENCY

*Note: There are other solutions with similar benefits to RFID/EPC systems - and potentially lower costs. However, these solutions are all proprietary, and therefore, they run the risk of less than industry-wide adoption.*

As with any business investment, the amount of money saved or earned must at least equal that of the amount spent. A November 2002 AMR Research study found that increased inventory visibility reduced supply costs 3-5% and improved revenues 2-7%. The savings grew out of improving the accuracy of shipments, lowering inventory carrying costs, and reducing shrinkage.

In early February of 2003, the Auto-ID Center released five new studies detailing business cases for implementing Electronic Product Code technology. One of the reports suggests that a company could save 35% in labor costs alone - RFID's ability to prevent theft and administrative error should add even more. Details on the reports can be found at [www.epcglobalinc.org](http://www.epcglobalinc.org).

## BENEFITS

The benefits of an RFID/EPC system are numerous, and they reward government, manufacturers, wholesalers, and pharmacies alike. In many instances, a single benefit applies to more than one constituent. This list of benefits is organized by the audiences.

### **BENEFITS TO ALL PARTICIPANTS IN THE SUPPLY CHAIN**

*Protecting Patient Safety: counterfeit and adulterated drugs*

A fake meningitis vaccine is thought to have caused an estimated 3,000 deaths in Niger in 1996. In Florida, pharmacists found white pills thought to be aspirin in bottles labeled Zyprexa®, a schizophrenia medication. The case is not an isolated

Note: At first glance, preventing fraudulent or adulterated drugs seems to fall more squarely within the category of government benefits. However, manufacturers are intimately associated with their brand. Even when brands are counterfeited, adulterated, or tampered with, the pharmacy, wholesaler, and manufacturer suffer the ill effects - enduring the press coverage and seeing their name repeatedly associated with the criminal action. Such press coverage erodes consumer confidence in the brand. It is a public relations debacle that is best avoided at all levels.

incident. Ten types of counterfeit drugs have appeared in that state in the past two years. In addition to counterfeit drugs, diluted drugs are making their way into the marketplace. Florida investigators seized vials of Procrit® and Epogen® that contained only one-twentieth of the active ingredient on the label. In South Florida alone, \$20 million in adulterated pharmaceuticals were seized last year.<sup>2</sup> A Minnesota pharmacist was quoted in **USA Today** as saying, "I've been in the business for 40 years. I have less confidence in the integrity of the supply line today than ever before. It scares me."

According to the WHO (World Health Organization), counterfeit drugs account for more than 7% of global pharmaceuticals, a percentage that translates into an estimated \$2 billion in lost sales for pharmaceutical companies. This number is lower than might be expected, considering that many developing countries have counterfeit rates as high as 40%. The global number is low because the dominant volume of drugs is consumed in the U.S., currently the safest market in the world. The safety of the U.S. offsets the high counterfeit rates elsewhere in the world.

However, as drugs grow more expensive, the allure of counterfeiting will grow stronger, threatening the nation's low numbers. As noted elsewhere in this paper, the number of counterfeit drugs in the U.S. has already increased in 2003. Some analysts speculate that organized crime and illicit drug dealers are entering the counterfeit prescription business in this country, and it stands to reason that they will focus their efforts on the home front, the world's most profitable pharmaceutical market. More organized counterfeiters in the U.S. will only enlarge the scale and increase the capabilities of the counterfeit prescription enterprise. We must take steps to strengthen our security to keep our numbers low.

Another danger that looms on the horizon is the threat of terrorist tampering. Whether this threat is real or imagined, there are consumers who worry about malice spurring counterfeiting/tampering activities. The national news recently reported that terrorist organizations have cited corrupting the nation's prescription drug supply as part of their overall plan of attack.

Many of the current drug imitations already appear so authentic that pharmacists find it difficult to distinguish the fakes from the genuine medications. As the price of new drugs escalates, producing cheap imitations promises lucrative rewards. The perpetrators of these crimes are producing sophisticated labels that credibly mask fraudulent pharmaceuticals. Adding to the problem is the circuitous, often byzantine, paths that drugs legitimately take in moving from one wholesaler to another, creating a secondary market. Further, drugs sold to physicians, alternate care facilities, and hospitals are sometimes illegally bought back - sold to unethical distributors at a discount - creating a black market. Such activity provides a perfect cover for imposters to enter and circulate in the marketplace.

The situation is alarming, and any breach of security within the drug system in America calls urgently for resolution. Indeed, the presence of counterfeit drugs within a fully implemented RFID network would virtually set off an alarm because of the way the system works. Two features discourage intruders. First, an EPC tag gives an authentic drug a singular identity within an RFID network. To create a counterfeit drug, perpetrators would have to create an identical EPC tag. A duplicate tag would immediately call attention to itself within the system. A second feature, tracing, follows a drug's movement from manufacturer to distributor to retailer/hospital, establishing a pedigree. Once again, the impostor drug would be instantly recognized as counterfeit because the duplicate drug would appear in an incorrect location within the system. An RFID/EPC system could have avoided the problems Florida experienced by keeping the pedigree of prescriptions clear.

<sup>2</sup> Julie Appleby, **USA Today**, May 15, 2003, p. 1A.

*Note: For a summary of all benefits of RFID/EPC systems, please see Appendix B.*

### *The Importance of Public Perception*

Americans are skittish in this post-9/11 era. They are more fearful of villainy that can occur from both inside and outside the nation. They want assurances that they are being protected. If the health care/pharmaceutical supply chain network fails to provide that protection, such inaction will garner ill will, damaging reputations of individual entities within the industry and the industry as a whole. This year, the public has witnessed a recall of more than 100,000 counterfeit bottles of Lipitor® as well as an attempt to sell batches of bacteria-tainted water masquerading as Procrit®.

**USA Today** reports a four-fold increase in counterfeit-drug cases in 2003. As the counterfeit drug industry becomes ever more lucrative - and it will, with genome-based pharmaceuticals entering the market - bogus and adulterated drugs will become a greater threat. To stymie these fraudulent activities and prevent medical tragedies attributed to human error, the supply chain constituents must stay alert to emerging technologies. When viable solutions present themselves, the healthcare supply chain is obliged to act in an ethical, responsible, effective, and responsive manner. The RFID/ EPC system's ability to track and trace will go far toward providing the desired security.

### *Simplifying Product Recalls*

Product recalls are particularly labor intensive and expensive. To retrieve a small percentage of tainted or defective products, all units must be recalled, a process that affects many parties within the supply chain. Staff must spend time searching for lot numbers that often were never received or have been long since gone. As a result, the entire supply chain faces increased pressure to wring out yet additional cost savings to compensate for the cost of the recall.

Because an RFID/EPC system can identify specific units and their whereabouts, the system can distinguish safe from unsafe units during a recall, retrieving *only* the affected units - thereby saving the supply chain time, effort, and enormous amounts of money. Currently, the practice is to return more items than actually necessary to eliminate any possibility of error.

### *Tracking Inventories*

Accurate and constant monitoring at item level reduces errors - malicious and non-malicious - throughout the inventory supply chain process. To be able to immediately "read" a pallet's contents without opening cases is a major advance in inventory efficiency. So is being able to turn on shelf readers and instantly know how much product is on-hand. Such practices reduce cost and labor for all constituents in the supply chain.

## **BENEFITS TO GOVERNMENT**

### *Reducing Recycling Costs*

The biggest cost of recycling is dealing with identifying and sorting plastic containers according to materials and color. RFID/EPC systems can read loads at a glance.

### *Tracking Imported and Re-imported Drugs*

Counterfeit or adulterated product can enter the system through foreign channels, increasing the demands on the US Customs Service, the DEA, and the FDA at a time when these agencies are also focusing their efforts on matters of homeland security. An RFID/EPC system provides a way to authenticate questionable drugs and free agencies to tend to other matters.

## **BENEFITS TO MANUFACTURERS, WHOLESALERS, AND PROVIDERS**

### *Effective Inventory Management*

Knowledge is power. When participants within the supply chain can see that goods

are available and know where they are within the supply chain, parties all along the supply chain can reduce their inventories, without risking sales.

Smart shelves with RFID/EPC readers will "know" how many units are on the shelves. When the number drops to a trigger point, the system alerts staff to replenish the shelf. At the retail level, replenishment can mean either retrieving additional stock from the storeroom or ordering more product. When the stockroom's stock levels fall below a certain point, the system can signal that it's time to contact the distributor or manufacturer.

#### *Keeping Stock Visible - Even When it's in the Wrong Place*

As frustrating as out of stocks are, it is even more frustrating to have the goods on-hand, but miss a sale because goods were misplaced and no one knew more stock was available. An RFID/EPC system always knows where goods are, even when they are stored in unconventional places or stored in error.

#### *Improving Flexibility in Storage*

Because an RFID/EPC system can always "find" the location of a product, goods can be stored anywhere on the premises. Overflow stock can be located in several places without getting lost or overlooked. Orders can be fragmented - shelved most efficiently without regard to losing track of the goods.

#### *Reducing Shrinkage*

Each year, the University of Florida conducts a National Retail Security Survey. The survey reveals that nearly 2% of the nation's sales are lost to shrinkage. RFID/EPC can reduce the incidence of shrinkage on all levels by providing real-time inventory visibility.

**Manufacturers and Wholesalers.** Processing and administrative errors account for approximately 78% of manufacturer shrink losses. An RFID/EPC system can monitor shrinkage accurately and instantly, correcting process errors at the point of occurrence. By matching EPCs arriving or leaving with the scheduled deliveries or shipments, real-time tracking recognizes inaccurate inventory audits and on-hand adjustments. It verifies internal and external department transfers, and it identifies delivery errors. All are ways to substantially reduce cost.

**Pharmacies.** By individually tagging all products, RFID readers can identify items as "purchased" or "not purchased," thereby reducing internal and vendor theft. Since product delivery quantities can be instantly read and verified, RFID/EPC systems also reduce supplier fraud, such as phantom deliveries, invoice errors, and over/under delivery. Lastly, non-malicious "paper shrink" such as pricing errors, scanning errors, and incorrect physical inventory can be automatically detected and corrected.

Moreover, if we broaden the scope of RFID/EPC systems, as seems natural, to include merchandise in the front-end of pharmacies, the technology would be particularly valuable in quashing shoplifting. Shelf readers can call attention to suspicious shopping behavior that takes place on department shelves. By alerting staff to the removal of multiple units of product, the system can avert the theft.

#### *Managing Stock About to Expire*

Many providers, wary of dispensing medications that are approaching their expiration date, "hold" these items rather than release them to retail outlets or patients. Storing these medications ties up millions of dollars in unproductive inventory. The items cannot be returned until they expire, and huge numbers of medications sit in warehouses, sometimes for as long as a year, depending on the policy of the organization.

To carry out these safety policies, today's providers check expiration dates manually, bottle-by-bottle, rather than risk releasing expired or nearly expired medication to a

patient. RFID systems, with their track-and-trace capabilities can automate this process, keeping medications "active" longer. Distributors who feel more confident about reducing the possibility of human error may be inclined to loosen their "holding" policies, shortening the time these medications are stored.

#### *Managing Returns*

Like shrinkage, accepting returns is another example of the costly price of doing business. RFID technology eliminates the expense of fraudulent returns because the returned item's EPC tag will confirm or deny its pedigree with unerring accuracy. In addition, RFID/EPC systems can track legitimate returns, thereby reducing unrecorded returns or preventing inaccurate calculations. The returns will automatically be entered into the system as debits and credits.

### **ADDITIONAL BENEFITS TO MANUFACTURERS**

#### *Supporting Valid Results in Drug Research*

The potential uses of RFID/EPC to ensure patient safety extend far beyond false pedigrees. For example, a similar system in packaging can be used to track compliance in clinical drug trials. A Swedish company has developed blister packaging that uses conductive inks to print circuits on the plastic bubbles that hold pills. As a patient breaks open each bubble within the blister pack, the package records the date and time, creating a record of drug usage. Additionally, a keypad could be used to record how patients feel after they take the pills. Electronic patient diaries could become key components in the clinical trial process. "Smart" packages hold all of this information until they are returned to a doctor's office where the data is downloaded to a PC using a tag reader.

#### *Reducing the Cost of Anti-theft Packaging*

The theft-prevention features of an RFID/EPC system would remove the need for manufacturers to protect small, high-ticket items by packaging them in expensive bubble clamshells.

#### *Other Uses*

- Prescription vials that report non-compliance when patients forget or refuse to take their medication.
- Prescription vials that remind patients to refill a prescription when the contents get low.
- Smart packages can "sense" the degradation of a medication. The potential for this technology is far-reaching.

### **ADDITIONAL BENEFITS TO THE PROVIDERS**

#### *Intelligence About Merchandising*

Behind the pharmacy counter, an RFID/EPC system could track the whereabouts of medications that are stocked or restocked in an incorrect location. The technology will prevent a common problem in pharmacies: false out of stocks. Pharmacies often needlessly reorder product when a bottle is on hand but has been misplaced.

If the technology extends itself to the front-end of the pharmacy, shelf readers will record not only when products are removed from shelves, but also when they are picked up and put back, providing a record of customer behavior on a shelf-by-shelf basis. Smart Shelves can help retailers identify peak purchasing hours and patterns. Shelf readers can track shopper response to promotions, recording unit movement that can be variously organized by product, store, region, or chain. Such intelligence helps match forecasts to demand and helps tailor future promotions to specific market segments.

#### *More Efficient Use of Pharmacists' Time*

The theft-prevention features of an RFID/EPC system enable retailers to move small high-ticket OTC items from behind pharmacy counters so that consumers can serve

themselves. Many pharmacists currently secure these items behind the counter to thwart theft. However, when customers want to look at these products, the pharmacy staff must bring the products out, not a productive use of their time.

#### *More Accurate Dispensing*

RFID has the potential to eliminate prescription errors and their attendant costs. Automatically reading the EPC on the medication bottle assures that the correct product is being dispensed.

## RISKS OF NON-ADOPTION

Given the recent Lipitor and Procrit recalls, virtually everyone connected with the healthcare industry understands that the supply chain needs a system that is as secure, intelligent, efficient, and responsive as possible.

Furthermore, if we as an industry do not recommend a practical efficient system, others who know less about our industry may impose a more cumbersome, less workable system on us. Although Florida's recently amended wholesaler licensure law contains a "pedigree paper" definition and a provision that appears to require a paper pedigree in 2006, the legislature and Department of Health are open to a technological solution. Numerous discussions took place with the department and legislators by HDMA and its Florida distributor members in crafting the law that was enacted. Because the department advocated for full pedigree on all products, a separate section of the bill was drafted broadly with the intention to allow for a technological solution and to meet the department's position on the issue. This section does not specifically recommend what the technological solution should be, but instead was left open and limited to say that effective July 1, 2006, distributors would be required to pass pedigree, tracing back to the manufacturer, on all prescription drug products they sell to other distributors and retail pharmacies. Though the department wanted this requirement to become effective a year earlier, it acquiesced to the distribution industry to allow time to develop and implement a technological solution.

## VIABILITY QUESTIONS

### **IS THIS TECHNOLOGY REAL AND ATTAINABLE?**

Wal-Mart is mandating RFID/EPC capability from its suppliers by 2005. A conservative company, cautious about its technology investments, Wal-Mart has always focused on cutting costs as a way to lower prices, thereby increasing sales.

Several companies have already piloted RFID/EPC systems: Coca-Cola, Gillette, Johnson & Johnson, Kraft, Procter & Gamble, Sun Microsystems, Unilever, and Wal-Mart. Tagged cases were shipped to and from selected distribution centers and retail stores in more than eight states. In one test, Procter & Gamble saw RFID-enabled product inventories automatically replenish the supply when inventory was running low.

Hollister Inc. in Tennessee has used an RFID network with quantifiable success. (See page 3.) Procter & Gamble's CIO, Stephen David is quoted as saying that RFID is a matter of economics and competitive advantage. Mr. David feels that a great benefit of RFID lies not just in the selling of retailers products, but providing them with the intelligence that the product will make possible.

Several companies have created radio frequency ID patient wristbands with an ultra-thin RFID tag embedded in them. Some companies are in the process of

developing low-cost RFID tags that track medical and surgical instruments such as scalpels, forceps, and so forth. Scanners in surgical suites will monitor patients before surgeries are completed to detect tags on any misplaced instruments that may still reside in patients. From hearing aids to medical records to glucose readers, RFID is already providing efficiencies and safety within the healthcare arena.

### **BARRIERS TO ENTRY - *Why hasn't the technology been implemented yet?***

1. **Standards creation.** The move by UCC and EAN to take over EPC Network is a giant step forward. UCC and EAN are well known, accepted standard-setting organizations whose association with the technology will validate it. In addition, at the EPC Symposium held in Chicago, September 15-17, 2003, EPCglobal announced the release of Version 1.0 of the EPC Network.
2. **Data ownership and sharing issues.** EPC will succeed only if issues surrounding the data are resolved. Without visible data, the true value of EPC's benefits described in this paper will never be realized. The Collaborative Commerce Committee will deal with this issue aggressively and propose recommendations. Rules for data sharing will need to be developed among industry and across the supply chain to ensure access to the data.
3. **Lack of detailed cost analysis.** Companies are having difficulty evaluating the cost/benefit analysis for EPC adoption. To help companies estimate expenses and evaluate benefits, EPCglobal at [www.epcglobalinc.org](http://www.epcglobalinc.org) has added a calculator to its web site. In addition, HDMA's Healthcare Foundation will be conducting a study in the pharmaceutical industry to truly evaluate this area.
4. **Technology considerations.** These issues are considered temporary obstacles that can be rectified.
  - Because RFID/EPC technology will track individual SKUs, some analysts speculate that the amount of data to be managed could increase significantly. A case in point: instead of scanning and tracking a single case of product made up of 24 units, the new technology would allow for tracking all 24 items when necessary. The question has arisen, *Do we have systems large enough to handle all the data?* Technologists and vendors are rapidly addressing these issues as of the writing of this paper.
  - There are issues in achieving a 100% read rate. Companies will need to determine the electromagnetic properties of products, packaging, and pallet configurations. Properties of certain packaging (e.g., fluids in vials) as well as properties of the product itself may hinder reading.
5. **Role of bar code technologies in an EPC environment.** Currently available bar code formats, such as RSS, will continue to have applicability in an EPC environment. RSS and other similar formats have an advantage: they can be applied to smaller package labels, such as unit dose tablets and capsules. For the near future, RFID/EPC tags may be too large to attach to individual unit doses within a box of 100 tablets. In addition, the technology to read the RFID tag on individual packages may not be readily available in a hospital of 500 beds, for example, which would likely require a minimum of several hundred readers to provide bed side medication identification. In addition, some details require further exploration: such as the potential incompatibility with existing RF and other such networks used in clinical monitoring and IS systems.

*"It is very fulfilling to see this technology begin its transition into commercialization. The launch of the EPC Network is a testament to the many minds around the world that created it and the support and vision of the more than 100 sponsor companies and organizations that supported our research over the years. We look forward to continuing our work with EPCglobal and its members to realize the potential of this technology."*

Sanjay Sarma,  
Chair of Research/Co-founder  
Auto-ID Center

### THE NEXT STEP

**The clock is ticking** - not only to comply with the FDA mandate but also to expedite a much-needed solution to safety and efficiency. RFID provides a viable solution. The Collaborative Commerce Committee invites interested volunteers, primarily manufacturers and wholesalers, to step forward to help refine and develop the new supply chain protocols. Collaboration is needed from all sectors of the supply chain to succeed and to move the process along.

**Taking action.** The effort will also need preparation within the supply chain constituencies. We hope that senior executives will encourage staff at all levels to begin to educate themselves about RFID/EPC technology and its implications for their organizations. Transitions never happen overnight. The process begins with preparation at all levels: committees of managers, IT technicians researching the topic, warehouse and loading dock supervisors thinking about how new systems may affect their current procedures and processes.

**Further study.** The committee needs volunteers who would form a commission to study pilots in more detail. In addition, we would like to engage a pharmacy school to collect pilot data and validate the results. On another front, further government regulations, both state and federal, need to be monitored. As the need arises, RFID/EPC proponents will be needed to speak to government representatives, presenting the case for this technology in a considered and cautious manner.

To pro-actively pursue ways to protect the nation's drug supply - and in so doing, ultimately protect the nation's patients - is the message that Americans want to hear. It is a message that must be supported by action that is genuine and practical. Improving the control of items in the health care supply chain is more than a response to a government mandate. It is an opportunity to make a statement about our industry, its vigilance, its responsiveness to the need for change, and its determination to accept only the "right" solution.

HDMA is working collaboratively with EPCglobal and Auto-ID Labs to further the education, adoption, and implementation of electronic product codes in healthcare distribution.

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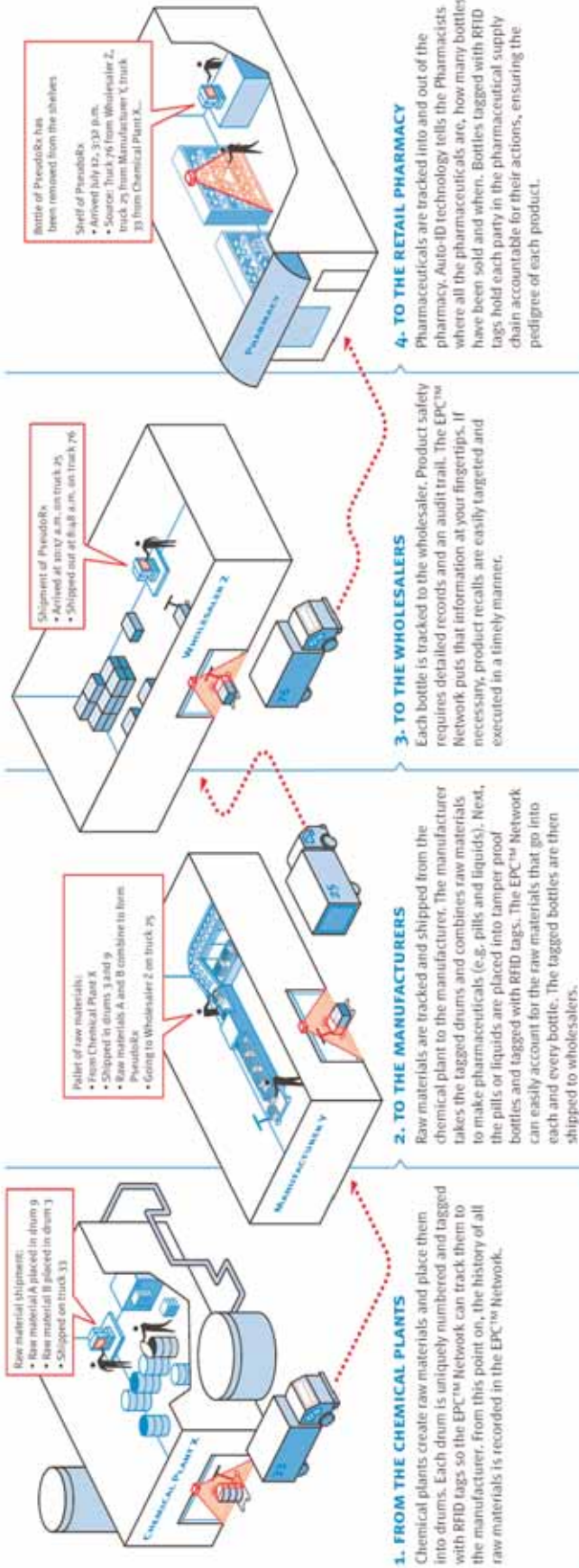
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**APPENDIX A:**  
The system

**XPLANATIONS<sup>SM</sup> by XPLANI**

**AN ACCOUNTABLE SUPPLY CHAIN: PHARMACEUTICAL PEDIGREE**

The pharmaceutical supply chain is a complex one. Not knowing the process by which pharmaceuticals make their way to pharmacy shelves can lead to risk in counterfeit products. Auto-ID technology helps manage this risk and maintain pedigree by tagging pharmaceuticals and product packaging with radio frequency identification (RFID) tags each possessing a unique EPC<sup>SM</sup>. This allows products to be tracked, traced and recalled if necessary.



**THE EPC<sup>SM</sup> NETWORK: HOW DOES IT WORK?**

With the new EPC<sup>SM</sup> network, manufacturers, distributors and retailers will be able to track and trace items automatically throughout the supply chain. Here's how it works:

**THE RFID TAGS**  
An Electronic Product Code (EPC<sup>SM</sup>) is embedded into microscopic "smart tags" and attached to an item's packaging (e.g. drums or bottles). These tags allow the items to be tracked in a completely automated, cost-effective fashion.

**THE READERS**  
Radio Frequency Identification (RFID) readers can scan each tag and send the item's EPC<sup>SM</sup> to a computer running Savant<sup>SM</sup>.

**SAVANT<sup>SM</sup>**  
Savant<sup>SM</sup>, middleware that connects the Auto-ID Applications Developer (OAD) to the Object Name Service (ONS) database.









































































**EPC<sup>SM</sup> Applications Developer (OAD)**

**ONS SERVER**  
The ONS links the EPC<sup>SM</sup> to a URL where all of the item's information is stored using Physical Markup Language (PML).

**PML SERVER**  
The PML server contains information about the item itself, its manufacturing, shipping and other related data.

**Pharmaceuticals produced in Dallas, shipped to New York.**

**APPENDIX B:**  
EPC Benefits Matrix

BENEFIT	GOVERNMENT	MANUFACTURERS	WHOLESALERS	PROVIDERS
				
Protecting Patient Safety: counterfeit and adulterated drugs				
The Importance of Public Perception				
Simplifying Product Recalls				
Tracking Inventories				
Reducing Recycling Costs				
Tracking imported and re-imported drugs				
Supporting Valid Results in Drug Research				
Reducing the Cost of Anti-theft Packaging				
Effective Inventory Management				
Keeping Stock Visible — even when it's in the wrong place				
Improving Flexibility in Storage				
Reducing Shrinkage				
Managing stock about to expire				
Managing Returns				
Intelligence about merchandising				
More Efficient Use of Pharmacists Time				
More Accurate Dispensing				

## APPENDIX C:

### Glossary

CIO:	Chief Information Officer
DEA:	Drug Enforcement Agency
EAN:	European Article Numbering
EDI:	Electronic Data Interchange
EMID:	Electromagnetic Identification
EPC:	Electronic Product Code
FDA:	(U.S.) Food and Drug Administration
HDMA:	Healthcare Distribution Management Association
MIT:	Massachusetts Institute of Technology
NDC:	National Drug Code
ONS:	Object Naming Service
PML:	Physical Markup Language
RFID:	Radio Frequency IDentification
RSS:	Reduced Space Symbology
UPC:	Universal Product Code
WHO:	World Health Organization
XML:	eXtensible Markup Language



