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Reviewing the drivers and challenges in RFID implementation in the pharmaceutical supply chain

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Abstract: Counterfeiting is a global phenomenon that poses a serious financial threat to the pharmaceutical industry and more importantly jeopardizes public safety and security. Different measures, including new laws and regulations, have been put in place to mitigate the threat and tighten control in the pharmaceuticals supply chain. However, it appears that the most promising countermeasure is track-and-trace technology such as electronic-pedigree (E-pedigree) with Radio Frequency Identification (RFID) technology. In this study we present a framework exploring the antecedents and consequences of RFID applications in the pharmaceutical supply chain. The framework proposes that counterfeiting and E-pedigree regulation will drive the implementation of RFID in the pharmaceutical supply chain, which in turn provides strategic and operational benefits that enable competitive advantage. Meanwhile, the implementation of RFID requires overcoming many operational, technical and financial challenges. The framework provides a springboard that future study can explore using empirical data.

Key Words: Electronic Pedigree, Radio Frequency Identification Technology, Counterfeit Pharmaceuticals, Pharmaceutical Supply Chain

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1 Introduction

According the World Health Organization (WHO), counterfeit drugs are defined as substandard pharmaceuticals which are mislabeled intentionally and fraudulently. Counterfeit drugs may include products with the correct ingredients with false packaging and may involve the absence or insufficient amount of active ingredients (WHO, 2006). In essence, counterfeit drugs are pharmaceutical products that possess qualities below the established standards, which render them ineffective for treatment of diseases and could be potentially hazardous or fatal to patients. This spreading phenomenon involves both branded and generic products. In the United States (U.S.), in 2004 the National Association of Boards of Pharmacy (NABP) created a "National

Specified List of Susceptible Products” (NABP, 2004: see Exhibit 1 in the Appendix). These drugs were designated and determined to be susceptible to adulteration, counterfeiting or diversion, and could potentially pose risks to the public health (NABP, 2004). Counterfeiting is much more widespread and can involve many drugs from different therapeutic classes. Drugs from different classes, regardless of their prices, have been counterfeited. Expensive lifestyle and anti-cancer drugs, antihypertensive and lipid lowering agents, antibiotics as well as drugs for life-threatening diseases such as HIV/AIDS or tuberculosis or malaria in developing countries were reported to be counterfeited (WHO, 2006; NABP, 2004). In addition, there have been reported cases of counterfeits of hormones, steroids and pain killers as well as inexpensive generic products. However, for the most part, the combination of expensive drugs and the relative ease of access to the supply chain put the pharmaceutical industry and patients at high risk (NABP, 2004).

In 2006, Intercontinental Marketing Services (IMS) Health identified four of the top ten leading branded drugs in sales volume as susceptible for counterfeiting by the NABP (IMS Health, 2007a; NABP, 2007). The cholesterol-lowering medication Lipitor had the highest sales in 2006 and was also on the National Specified List of Susceptible Products. To put the financial impact of counterfeiting in perspective, if Pfizer lost just one percent of Lipitor sales to counterfeiting it would cost them 136 million U.S. dollars, which is money that cannot be used to recoup the investment in the development of Lipitor and to develop new drugs. Different measures, including new laws and regulations, have been put in place to mitigate the threat and tighten control on pharmaceuticals as they travel throughout the supply chain. However, it appears that the most promising countermeasure is establishing track-and-trace technology such as electronic-pedigree (E-pedigree) with Radio Frequency Identification (RFID) technology.

Radio frequency identification systems have been used in the manufacturing environment since the early 1990s as a way to control and track products moving on assembly lines, and the part bins that feed the line (Stall, 1993). These early manufacturing implementations of RFID utilized proprietary systems that were internal to the organization. As RFID technology around standardized open systems evolved and costs decreased, other RFID applications became feasible, drawing the interest of additional supply chain entities. Industry mandates by Wal-Mart (O'Connor, 2005) and the U.S. Department of Defense (Collins, 2004a) provided the motivation to expand RFID systems beyond the factory walls to include suppliers, logistics providers and customers.

Our discussion of RFID systems focuses on the use of passive, chip-based, read-write tags which provide a 'living history' of the item being tracked and therefore have the potential to increase the transparency of items moving through a manufacturing facility and the supply chain (Li and Visich, 2006). However, this 'living history' is stored in a secure database, not on the chip as will be explained in the next paragraph.

In an RFID system a unique identifier, such as an EPC or an e-Pedigree, is embedded into the micro-chip in a tag. The tag is then attached to the item being tracked. As the item moves into the scanning range of the reader, the reader sends out electromagnetic waves that form a magnetic field when they 'couple' with the antenna on the RFID tag. The tag draws power from the magnetic field and uses it to power the micro-chips' circuits. The micro-chip then modulates the signal received in accordance with its identification or programmed code and transmits or reflects a radio frequency signal. The modulation is in turn picked up by the reader, which decodes the information contained in the transponder, and depending upon the reader configuration, either stores the information, acts upon it, or transmits the information to the host

computer via the communications port (Jones *et al.*, 2004). It is the database linked to the host computer that records and stores the history of the tagged item. For a detailed discussion on how RFID systems operate see Dinning and Schuster, 2003; Jones *et al.*, 2004; Srivastava, 2004; Angeles, 2005; or Li *et al.*, 2006.

Because RFID tags include tiny micro-chips that can store more information compared with bar-code technology, the U.S. Food and Drug Administration (FDA) considers RFID a more promising technology as a means to achieve e-pedigree (FDA, 2004). E-pedigree systems depend on technology that would carry the serialized information to automatically identify each bottle or vial (Focinio, 2007) and RFID technology can be used to identify pharmaceuticals at the item level. The Serial Number portion of the EPC on a 96-bit tag is reserved to identify the unique product item and it has the capacity to uniquely identify nearly 69 billion items for a single stock-keeping-unit (Brock, 2001). In addition, RFID tags can provide real-time information with a capability of reading multiple items simultaneously with no direct line of sight to reader. In contrast, bar codes have a limitation of reading one item at a time and the scanner has to be in a direct line of sight with the bar codes, which can be labor intensive (Wilding and Delgado, 2004).

RFID could provide benefits to all partners in the pharmaceutical supply chain, including manufacturers, distributors, retailers and hospitals. Most importantly, patients and the public at large will benefit from this technology. The use of RFID will improve the tracking of drugs as they travel downstream in the supply chain, improving product visibility thereby making it easier to detect counterfeiting and the malicious insertion of poisonous drugs by terrorists (Wicks *et al.*, 2006). In addition, RFID could provide customer and patient security at the point of sale or dispensing. According to the Pharmaceutical Research and Manufacturers of America,

“electronic authentication at the dispensing level provides a direct means of determining in real-time whether a particular packaging unit is authentic (PhRMA, 2005).”

Regardless of increased attentions to RFID and many proposed benefits of RFID implementation in the pharmaceutical supply chain, few studies have provided an integrated view of RFID implementation in the pharmaceutical industry. To fill this gap, this study developed a framework exploring the antecedents and consequences of RFID applications in the pharmaceutical supply chain (see Figure 1). This study provides a comprehensive evaluation of the potential and challenges of RFID and thus offers useful guidelines for pharmaceutical companies who are interested in adopting this technology. Moreover, this study offers a framework that future study can explore.

The paper is organized as follows. We first present our framework. Next, we discuss the drivers of RFID implementation in the pharmaceutical supply chain, followed by a discussion of various applications of RFID, associated benefits and the challenges of implementing RFID. We end our paper with research implications and our concluding thoughts on RFID systems in the pharmaceutical supply chain.

INSERT FIGURE 1 ABOUT HERE

2 Framework for RFID implementation in the pharmaceutical supply chain

Figure 1 proposes that counterfeiting and E-pedigree regulation will drive the implementation of RFID in the pharmaceutical supply chain, which in turn provides strategic and operational benefits. Strategic benefits include counterfeit prevention, recall precision, reimbursement compliance, and brand protection. Operational benefits consist of ship and receive, labor and inventory, Prescription Drug Marketing Act (PDMA) compliance and loss prevention.

Meanwhile, the implementation of RFID requires overcoming many operational (tag positioning, liquid and biological tagging, read rate, and interference between wireless medical devices), technical (lack of standard for E-pedigree and inconsistent tag frequency), financial (cost of implementation) and other challenges (privacy concern). We now discuss the drivers for RFID implementation in the pharmaceutical supply chain.

2.1 Counterfeiting

According to IMS Health (2007b), the global pharmaceutical sales market in 2006 was estimated to be U.S. \$643 billion. The WHO has estimated counterfeit drug sales as a percentage of total drug sales to be about 1% in industrialized nations and up to 10% in some developing countries, which is substantial and poses a threat to the profitability of the pharmaceutical industry. It was also predicted that counterfeit drug sales would increase by 90% from 2005, reaching about \$75 billion globally in 2010 (WHO, 2006). Though the prevalence of counterfeit drugs in the U.S. is unknown, it has become a growing problem.

In the U.S., the number of FDA counterfeit investigations has increased significantly over recent years. The frequency of counterfeit investigations was 58 in 2004, an almost six-fold increase from 1997 (Lutter, 2005). However, in 2005, the FDA's Office of Criminal Investigations (OCI) initiated 32 counterfeit drug cases, a significant decrease from the year before. This could be in part due to an increased awareness and vigilance at all levels of the drug distribution chain and due to increased coordination with other state and federal law-enforcement agencies and better communication with drug manufacturers (Lutter, 2005). Or, due to the inability of regulatory agencies and the pharmaceutical supply chain to track and trace drugs, counterfeiters might be using new methods that are more difficult to detect.

According to Patton (2006), the global pharmaceutical industry is heavily regulated. However, the rules as well as prices are different from one country to another, which tends to foster illegitimate business. In the U.S., the wholesale pharmaceutical business is primarily controlled by three main wholesales: Cardinal Health, McKesson, and Amerisource Bergen, which have a market share of over 90%. The rest of the market is shared by hundreds of wholesalers that serve as legitimate businesses in moving excess inventory from large distributors to the next customer in the supply chain. These smaller businesses increase the complexity of the pharmaceutical supply chain which reduces visibility and creates an opportunity for counterfeiters to enter the supply chain (Patton, 2006). In industrialized nations, internet-based sales pose a major threat to the pharmaceutical supply chain as they provide an easily procured source of counterfeits from different countries (WHO, 2006). In the U.S., the illegal importation of drugs through internet sales from Canada or Mexico poses a threat to patients and the public who seek cheaper and unauthorized drugs with unknown origins.

2.2 Government regulation and E-Pedigree

In the U.S., the pharmaceutical supply chain stakeholders as well as U.S. state and federal officials have recently collaborated on establishing countermeasures to mitigate the risk of counterfeiting and tighten control on pharmaceuticals to increase security and protect the public. The most promising countermeasure is establishing track-and-trace technology such as electronic-pedigree (e-Pedigree) with RFID technology.

2.2.1 U.S Counter Drug Task Force

Counterfeiting seems to be the greatest in regions or countries with weak legal and regulatory structure (WHO, 2006). In the U.S., federal and state law enforcement agencies and in collaboration with all stakeholders in the pharmaceutical industry are devoting more efforts and recourses to combat counterfeiting. The U.S. Counter Drug Task Force has outlined countermeasures to protect the pharmaceutical supply chain such as the adoption and enforcement of strong laws and regulations, increasing criminal penalties to deter counterfeiting, securing business practices, implementing new technologies including “track and trace” and authentication of drugs in the supply chain, educating the public and health care professionals, and developing effective methods of reporting counterfeit pharmaceuticals (FDA, 2004).

2.2.2 U.S. federal laws and the Prescription Drug Marketing Act

On the federal level, the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992, has mandated requirements that every drug must have a full pedigree. A drug pedigree is a statement of origin, which provides the chain of custody of drugs as they are purchased, sold, or traded. This was needed as a method of accounting for the origin of pharmaceuticals and a verification of legitimacy. All involved parties names and addresses, and dates of transactions have to be identified and included for each sale of a drug. The main purpose of the PDMA is to tighten security and address problems of drug counterfeiting in the pharmaceutical supply chain (FDA, 1987; FDA, 1992). In essence, the PDMA set the guidelines to ensure the safety and authenticity of drugs as they move throughout the pharmaceutical supply chain.

The PDMA and existing regulations do not require any particular technology for pedigrees such as bar-code, RFID or other technologies. However, the FDA made a clear statement in its February, 2004 *Combating Counterfeiting Drugs* report that RFID represents one of the most important tools to help improve the safety of the drug supply chain (FDA, 2004). Furthermore, the FDA had requested the pharmaceutical industry to pilot track-and-trace solutions based on RFID and related technologies such as mass serialization and electronic pedigrees (E-pedigree) by the end of 2007. Mass serialization involves assigning an electronic product code (EPC) to each pallet, case, and individual package of drugs, thereby providing an E-pedigree that can be tracked from manufacturing to dispensing. And, the FDA has set January 2010 as the deadline for the implementation of a pedigree system (Swedberg, 2008). In addition, industry associations such as the Healthcare Distribution Management Association (HDMA) have published position statements advocating the accelerated adoption of electronic track and trace using EPC tagging. Specifically, the HDMA advocated the adoption at the case level by the end of 2005 and at the selling unit level by 2007. At the same time, RFID standards groups such as EPCglobal were exploring what standards and new practices need to be established to adopt electronic track-and-trace technologies throughout the supply chain (FDA, 2004). More recently, EPCglobal ratified a new E-pedigree standard, which is designed to aid companies in complying with mass serialization and E-pedigree regulations (EPCglobal, 2007).

2.2.3 U.S. state laws

On the state level, stronger requirements to safeguard the drug supply chain have been adopted by some states such as Florida and California. Florida has taken the lead by passing legislation that pharmaceutical product tracking and tracing should be embraced through the accumulation

of a paper-based product pedigree, detailing specifics about the supply chain history of each drug shipment. In 2006, Florida expanded its requirement for paper-based pedigrees as a first step and subsequently established a system of E-pedigree verification utilizing electronic data interchange (EDI) (Koroneos, 2007). Thus the system that has been established by Florida has been applicable to both paper-based and E-pedigree in the pharmaceutical supply chain. More recently, Florida has pushed for an electronic signature and verification version for pedigrees (Farber, 2007). In addition, California, Nevada and Virginia have also adopted laws to mandate some sort of pedigree for each drug sold in these states, which would require chain of custody from manufacturing to dispensing (Wasserman, 2005). California enacted an E-pedigree law that would mandate pharmaceutical companies, wholesalers, and hospitals to use electronic traceability for pharmaceuticals by early 2009. However, the law did not specify the use of RFID tags (Farber, 2007). Wholesalers in California opted for the more advanced electronic product code information system (EPCIS), which relies on web based connections rather than a single point connection such as EDI (Koroneos, 2007). Recently, due to industry pressure, the California State Board of Pharmacy decided to delay implementation of its E-pedigree requirement until 2011 (Swedberg, 2008). In addition to these efforts, the NABP made some efforts to revise the Model Rules, in order to strengthen the requirements for wholesalers as well as establish stricter measures to ensure and protect the pharmaceutical supply chain (FDA, 2004).

2.2.4 European regulatory views

Currently there are no regulations in the European Union (EU) requiring the use of e-pedigrees to track pharmaceuticals. A 2005 European Federation of Pharmaceutical Industries and

Associations report pronounced RFID as too expensive for item level drug tracking until at least 2010, recommending 2D barcodes for mass serialization in the interim (Harrop, 2007). The Italian government has proposed an initiative to require the use of dual bar coding (called bollino) to facilitate the reporting of sales data within 24 hours of any transaction along the supply chain. The regulation is meeting resistance from the Italian pharmaceutical industry because the use of bollino would slow productivity since high-volume scanners have not yet been developed (Wasserman, 2005). The lack of regulations and guidance from EU legislators means the European pharmaceutical industry will have to take the lead to reduce counterfeiting and protect the public safety.

3 RFID implementation and benefits in the pharmaceutical industry

Manufacturers, wholesalers and retailers have recently conducted pilot programs and undertaken major initiatives to evaluate benefits and the costs associated with RFID technology in the pharmaceutical supply chain. Figure 2 shows the supply chain for drugs in the United States. Note that direct-to-consumer web sales from foreign based firms are not part of this supply chain.

The potential benefits of adopting RFID technology to achieve e-pedigree in the pharmaceutical supply chain can be divided into strategic and operational benefits (see Table 1). For manufacturers, RFID technology could offer brand identity protection, reduce the risk of product tampering, decrease losses of theft and counterfeiting, and enhance product cycle information. For wholesalers, there will be increased efficiency in managing logistics and inventory. Retailers will increase patient confidence in their products, increase accuracy in their fill rate, and improve visibility and inventory management (Gebhart, 2007; Wicks *et al*, 2006;

Anonymous, 2004). The following section will discuss RFID initiatives and corresponding benefits from manufacturers, distributors/wholesalers, drugstore and retailers, and hospitals and health care providers respectively.

INSERT FIGURE 2 ABOUT HERE

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3.1 RFID initiatives from manufacturers

Wal-Mart, which has a pharmacy division and has been the leader in implementing RFID, as well as the U.S. Department of Defense (DOD) have ordered all their pharmaceutical suppliers to tag their products (Wasserman, 2005). Major initiatives to deploy RFID technology began early by key players in the pharmaceutical industry such as Pfizer, Purdue, Merck, Novartis and AstraZeneca.

In early 2006, Pfizer began to place RFID tags on all units of Viagra (erectile dysfunction drug) sold in the U.S., including bottles, cases, and pallets. The drug's popularity and high volume sales (over \$1.68 billion & \$850 million in 2004 and 2005, respectively) made it an attractive target of counterfeiters and therefore a prime opportunity for RFID-based counterfeit prevention (Wasserman, 2005; IMS Health, 2006). Pfizer focused on EPC authentication as a mean of deterring counterfeiting, which is a system that is not a track-and-trace solution nor is an e-pedigree system. Companies such as Purdue, GlaxoSmithKline, Merck and Novartis as well as others are running pilot programs to tag individual drug items in order to detect dispensing errors and counterfeiting before reaching patients. Purdue Pharma was one of the first in the industry to begin individual RFID tagging of Oxycontin (schedule II narcotic) bottles (Wasserman, 2005).

AstraZeneca also took a proactive approach to RFID by participating in the standards setting process, led through EPCglobal, and through the planned execution of a pilot in 2006. The pilot study involved using both RFID tags and bar codes to provide serialization of individual items and cases to protect its widely sold drug Nexium from tampering and counterfeiting (Demetrakakes, 2005; Lewcock, 2007). In 2006, GlaxoSmithKline attached RFID tags to all bottles of its HIV drug Trizivir (abacavir/lamivudine/zidovudine) distributed in the U.S. as part of a patient safety pilot project (Anonymous, 2006). The company chose Trizivir for the pilot because it was listed on NABP's list of the most susceptible drugs to counterfeiting and diversion (see Exhibit 1 in the Appendix). Many of the results of these pilot studies were shared with the FDA, but have not been shared publicly or published.

3.2 RFID initiatives from distributors and wholesalers

After drugs are manufactured and tagged, they are moved downstream to wholesalers and then to retailers' distribution centers in pallets and cases (see Figure 2). In turn, most of wholesalers or retailers distribution centers ship small quantities of different drugs to hospitals or retailers by bottles grouped in totes. As required by state laws, distributors and wholesalers are required to provide some type of pedigree documenting the chain of custody, lot number and expiration date of each drug sold. Cardinal Health, one of the largest U.S. wholesalers, recently concluded an RFID pilot program, which included tracking pharmaceuticals at all levels. Their pilot program revealed that the technology read rate is very reliable at the item level. In their pilot, they utilized EPC Gen 2 UHF (Ultra High Frequency) tags to track pallets, cases and individual items, and they attained a read rate of more than 99% (Bacheldor, 2006). Early in 2007, Cardinal Health announced it would integrate RFID technology into its pharmaceutical distribution center

operation at Sacramento, CA. by fall of 2007. This is in preparation for California's pedigree mandate that will require all drugs distributed in the state to be tracked and traced at each step throughout the supply chain (Cardinal Health, 2007). Distributors have been trying to overcome some technical and business process issues (discussed later) before the widespread adoption and implementation of RFID.

3.3 RFID initiatives from drug stores and retailers

Retailers embarked on RFID technology in order to enhance compliance with the pedigree regulations. In an early pilot study, dubbed Project Jumpstart, manufacturers including Abbott Laboratories, Pfizer, Johnson & Johnson and Procter & Gamble shipped bottles of RFID tagged pills to distributors McKesson Corp. and Cardinal Health who then shipped to CVS and Rite Aid retail pharmacies (Whiting, 2004). The results showed that RFID could help satisfy both regulatory and retailer requirements, increase product security and consumer safety, enhance order accuracy and labor productivity as well as increase efficiency, and speed of recalls and returns. These findings were based on shipping, tracking and tracing of nearly 13,500 packages of pharmaceuticals over an eight week time frame. Thus, this project created the initial steps towards innovative approaches to address key issues such as mitigating the risk of counterfeiting and increasing supply chain visibility within each organization and across partners in the pharmaceutical supply chain to comply with the new regulations. The group also worked with the FDA's Anti-Counterfeiting Task Force to improve the pharmaceutical supply chain integrity, which is a high priority of the FDA. Furthermore, HDMA and the National Association of Chain Drug Stores (NACDS) were involved with this effort and provided the rest of their members

with information and educational material based on the results . However, these tests did not involve consumers (Anonymous, 2004).

3.4 RFID initiatives from hospitals and health care providers

In the healthcare system, there is an increasing interest in reducing the high rate of medical errors in order to improve patient safety through the utilization of RFID technology. Additionally, RFID could be utilized for inventory control, asset management, as well as to capture and provide accurate data about patients including identification and movement. Many hospitals use RFID to identify infants and match them with their parents (Ashar and Ferriter, 2007). RFID could also be used for tracking and matching blood for transfusions, and combating the counterfeiting of medical products (Wicks *et al.*, 2006). More importantly, it is becoming part of electronic medical records, as information is stored on the RFID tag, which could accompany patients. In a recent pilot study, RFID was utilized to ensure the quality, security and accuracy of prescribing and administering complex and critical drugs such as chemotherapeutic agents (Spahni *et al.*, 2006). Making use of all traceability data acquired from prescription to preparation to administration validate in real time that the right drug and dose are being given to the right patient at the right time, and can also record who handled the drug. Furthermore, potential long-term applications of RFID are to capture data generated from medical devices such arterial blood pressure and other cardiac monitoring parameters and making them available as part of the electronic medical records (Ashar and Ferriter, 2007).

RFID was also tested by the U.S. Navy to track and provide information about wounded soldiers in the battlefield (Schwartz, 2004). A similar system was also piloted in a hospital in an operational environment in Iraq, which resulted in the accurate documentation of casualties,

increased awareness of patient needs, and also maximized resources (Collins, 2004b). This system can be applied to an emergency response system, where speed and accuracy of treatment are critical to the patient's health (Wicks *et al.*, 2006).

4 Challenges with RFID adoption in the pharmaceutical supply chain

Pharmaceutical companies are faced with many operational, technical and financial challenges in adopting RFID (see Figure 1).

4.1 Operational challenges

Companies are required to label not only pallets and cases but also each drug bottle to create a system that will allow for authentication. It becomes even more challenging to decide where to position the RFID tag on the bottle in order to be read within a case or pallet. Additionally, tagging must be automated because of the huge volume of bottles that move through the packaging line. There are also concerns about the speed and accuracy of electronic devices and systems. Failure read rate can happen especially with vials made of metals and or containing liquids (Patton, 2006). Tagging liquids and biological products will be even more challenging due to space issues on the exterior of bottles and vials and also due to the questionable effect of radio waves on these products. Studies have shown that radio waves do not affect drugs in solid form, however, there are no studies published to date that look into the effect of radio waves from RFID tags on the stability and potency of liquids and biological products (Patton, 2006; Wasserman, 2005). In hospitals, RFID technology has the potential to interfere with wireless communications of medical devices, especially if the same frequency is used (Ashar and Ferriter, 2007). In January of 2007 the FDA issued a draft guidance report on the design, development

and testing of radio frequency wireless technology in medical devices. The focus of the report is to protect patients and operators from adverse effects caused by interference between wireless medical devices (FDA, 2007).

4.2 Technical challenges

Technical issues include the lack of consensus on standards for e-pedigree fields and formats, data systems, frequency and international transmission systems as well as software and hardware specifications (FDA, 2006). However, in January of 2007, EPCglobal ratified the new e-pedigree document standard, which should help companies to serialize products using EPC technology and thus comply with a wide variety of pedigree regulations. Establishing e-pedigree standards should also resolve the interoperability issue of exchanging document-based pedigrees. Moreover, EPCglobal has started working on developing a full track and trace system based on the EPC Information Services (EPCIS) standard, allowing the information to be shared upstream and downstream in the pharmaceutical supply chain (Harrison, 2007).

Unlike the U.S. and Europe, where the EPCglobal is the standard, Asian countries, including China, use their own classification systems. China supports the National Product Code (NPC), which is its own EPC-classification system for labeling products. Japan also uses a different standard, which does not communicate with the standard set by EPCglobal. Thus, standardization on a global level is still challenging and might take several years to overcome (Fish and Forrest, 2007).

Tag frequency is another technical issue that is not consistent worldwide. Both Europe and the U.S. use UHF in the range from 868 MHz to 915 MHz, respectively, while Japan uses UHF for RFID at a higher frequency than 915 MHz (Fish and Forrest, 2007). China has not accepted

UHF at these frequencies because they are designated for telecommunications, radio broadcasting and aerospace (Hotchkiss, 2005). Instead, China's Ministry of Information industries has approved bandwidth in the 840.25 to 844.75 MHz and 920.25 to 924.75 MHz ranges for passive tags (Swedberg, 2007). These inconsistencies among different countries could increase the cost of implementation of RFID due to an increase in reader complexity and other hardware components to handle different frequencies.

4.3 Financial challenges

Though RFID technology can improve efficiency in the supply chain, cost becomes an issue, especially when tagging low cost items. Therefore, it would be prudent to apply such technology to high priced drugs to reduce cost in relative terms. Pfizer spent \$5 million just to set up the tracking system for Viagra (Gebhart, 2007). A study by HDMA demonstrated that the startup cost of RFID for large pharmaceutical manufacturers and distributors would be \$15-20 and \$9-20 million, respectively. However, it was also estimated that on an annual basis pharmaceutical manufacturers and distributors would gain from \$500 million to \$1 billion and \$200-400 million, respectively, with wide adoption of RFID technologies (Wasserman, 2005). Tag costs are dropping and are highly dependent on volumes purchased and prices can vary from one country to another. For example, passive tags in the U.S cost about 7 cents versus 10 cents in Europe and up to 30 cents in Asia (Fish and Forrest, 2007). It is clear that more studies are needed to fully evaluate the business case for RFID, beyond the safety and compliance issues.

4.4 Other challenges

Privacy and data sharing are major concerns, especially for patients. Health care providers and pharmacists need to be aware of and be compliant with the U.S. Department of Human and Health Services Insurance Portability and Accountability Act (HIPAA) to safeguard patients' medical information (Wicks *et al.*, 2006). The American Civil Liberties Union and Consumers Against Supermarket Privacy Invasion and Numbering (CASPIAN) have raised concerns over tracking patients' medications and invading their privacy through the use of RFID in the retail setting (EPIC, 2007). Currently this is not an issue at the retail level because RFID tags are placed on large bottles that retailers buy and not on the individual containers that are dispensed to customers (FDA, 2006). Additionally, security measures can be applied to the RFID tags to prevent the accessibility of confidential patient information (Wicks *et al.*, 2006).

There are also major concerns about the ownership of the confidentiality of the business transaction data as it travels through the supply chain. It is critical for partners in the pharmaceutical supply chain to be able to share information in order to ensure a successful transmission of e-pedigree throughout the supply chain (Forcinio, 2007). Moreover, it is the consensus of the FDA that it is essential for each partner in the supply chain to have access to the pedigree information, starting from the original manufacturer. The FDA also wants pedigree access in order to monitor suspicious or illegal activity (FDA, 2006).

5 Research limitations, implications and future research

This review of RFID and the pharmaceutical supply chain provides a comprehensive evaluation of the potential of RFID among all stakeholders in the supply chain. It provides practitioners information about RFID technology, and its utilization and potential benefits in the

pharmaceutical supply chain and healthcare system. Additionally, it increases the level of awareness about the issues facing the pharmaceutical supply chain such as: the scope of counterfeit pharmaceuticals and the importance of increased vigilance and tighter control on pharmaceuticals as they travel throughout the supply chain; the legal and regulatory mandates; and the implementation challenges with RFID technology, including the technical, security and privacy hurdles. We attempted to present a balanced and comprehensive view of the issues. However, we had to rely primarily on non-peer reviewed literature due to the lack of peer reviewed publications related to this topic, which could have confounded our conclusions and presented some biases towards RFID. And, most RFID pilot study results were shared privately with stakeholders and were not made available to the public, especially the cost-benefit analysis. Beyond the mandates, it is clear that more controlled studies are needed to fully examine the cost-benefit ratio and the return on investment of RFID at all levels in the pharmaceutical supply chain. It is also crucial for the results of studies to be shared with all stakeholders, including the public.

We provide a framework (see Figure 1) that future study can use to create a conceptual model and theoretical propositions that can be investigated using field research and empirical data. This model could also posit how implementation of RFID might lead to competitive advantage. Another study could investigate how RFID can mitigate the risks to the pharmaceutical supply chain. Research could also focus on the level of implementation and how the benefits change as RFID is deployed. We hypothesize that the benefits of RFID will increase as RFID is implemented at more points along the pharmaceutical supply chain shown in Figure 2. And, that the greatest benefits will occur when RFID is deployed in the entire supply network. Such studies can deepen our understanding of RFID adoption in the pharmaceutical supply chain

and offer empirical justification for the benefits and challenges discussed in the non-peer reviewed literature.

6 Conclusion

The safety and security of the pharmaceutical supply chain hinges on the visibility and accountability of the drugs as they travel downstream in the supply chain. Compliance with PDMA is essential and the supply chain will have to capitalize on the advances of electronic track-and-trace based on RFID, as it appears to be the most promising technology to create e-pedigree. However, RFID technology is still emerging and the pharmaceutical supply chain needs to overcome the associated challenges to fully realize the wide range of benefits associated with the implementation of RFID, beyond the mandates. It is also critical to conduct more studies to justify the business case for RFID, since RFID technology provides an opportunity to improve supply chain efficiency and more importantly, public safety.

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Figure 1. RFID Implementation in the Pharmaceutical Supply Chain

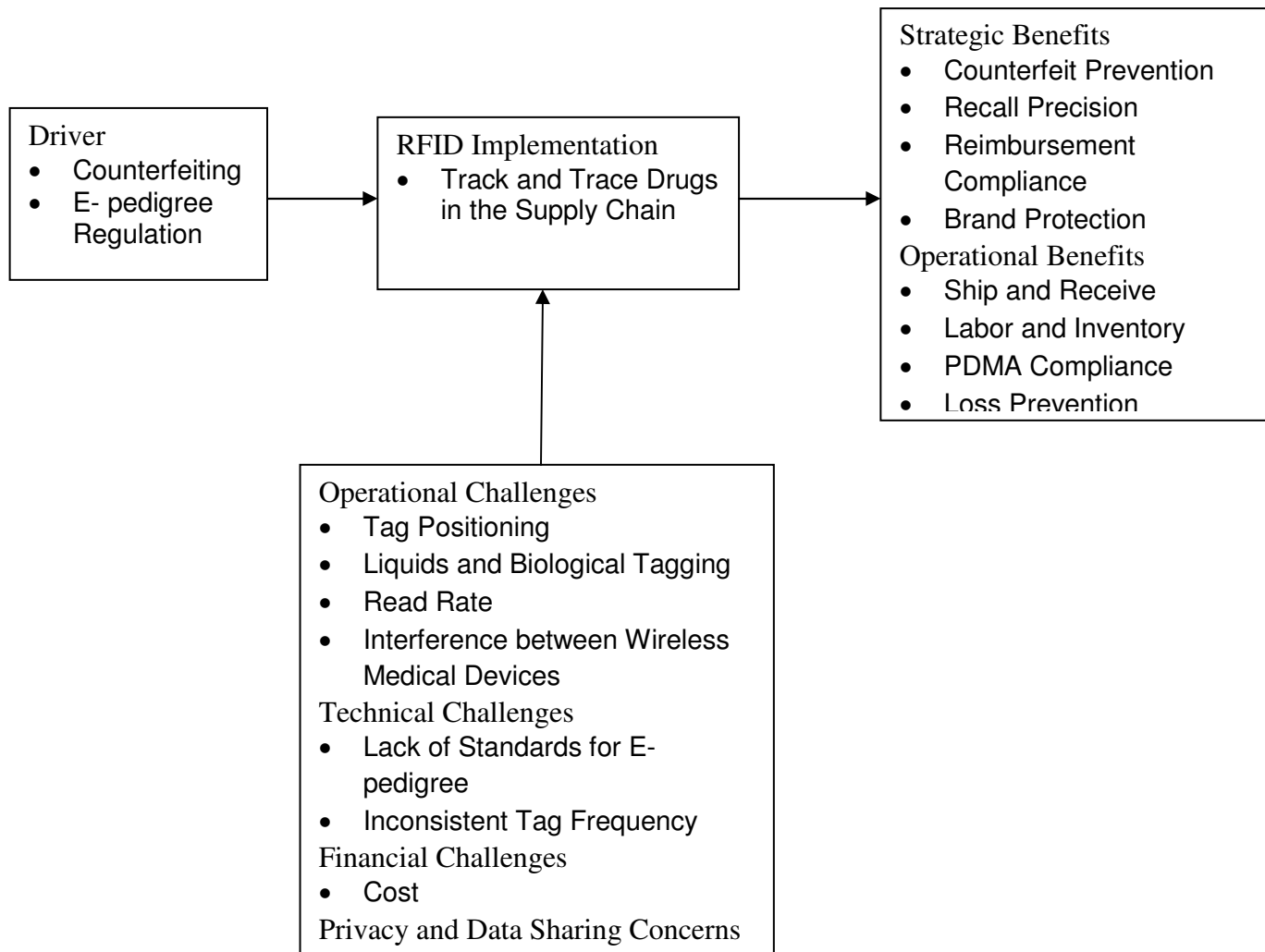


Figure 2 Diagram of the Flow of Drugs in Pharmaceutical Supply Chain

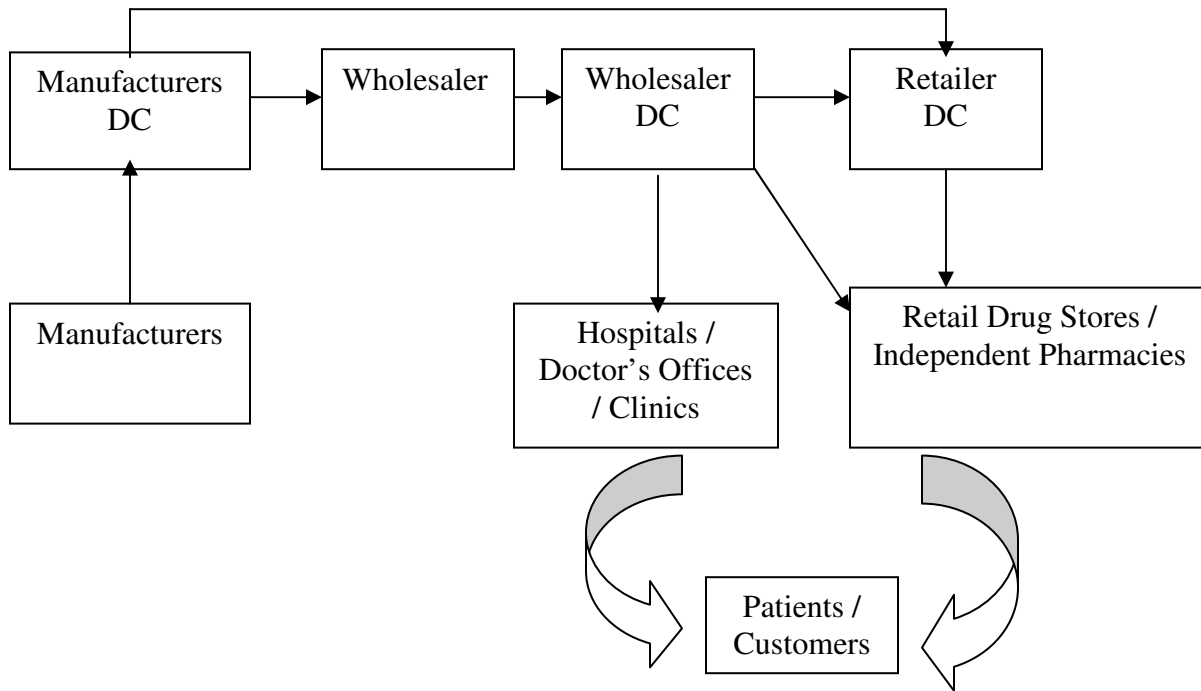


Table 1. Strategic and Operational Benefits of RFID and e-Pedigree

| | Manufacturers | Distributors/ Wholesalers | Retailers | Hospitals | Public |
|---------------------------------|---|--|---|---|---|
| Strategic | | | | | |
| Counterfeit Prevention | Prevention of tainted raw materials | Prevention of tainted bulk containers | Prevention of tainted bottles | Prevention of tainted bottles/vials | Increased awareness and safety measures |
| Recall Precision | Track and trace raw materials from receiving to distributor and drugs from distributors | Track & trace drugs from manufactures to retailers and back | Track and trace drugs from distributors to patients and back | Track and trace drugs from distributors to patients and back | Increased safety by alerting patients of tainted drugs |
| Reimbursement Compliance | N/A | N/A | Increased accuracy of reimbursements and decreased paperwork & errors | Increased accuracy of reimbursements and decreased paperwork & errors | Increased accuracy of reimbursements and decreased paperwork & errors |
| Brand Protection | Protects brand image, safety, reputation & profitability | Promotes safety | Promotes Safety and increases consumer confidence | Promotes Safety and increases consumer confidence | Promotes Safety and increases Consumer confidence |
| Operational | | | | | |
| Ship & Receive | Provides faster and accurate shipping & receiving | Provides faster and accurate shipping & receiving | Increased accuracy of fill rate and reduce medication errors | Increased accuracy of fill rate and reduce medication errors | Increased safety and decrease adverse events |
| Labor & Inventory | Decreased costs of labor and inventory | Decreased costs of labor and inventory | Decreased costs of labor and inventory | Decreased costs of labor and inventory | Decreased prices |
| PDMA Compliance | Increased compliance | Increased compliance | Increased compliance | Increased compliance | Increased safety |
| Loss Prevention | Increased security of raw materials, work-in-process and finished goods in storage | Increased security as product is transported downstream and is stored in the warehouse | Increased security against employee theft and customer shoplifting | Increased security against employee theft | Decreased prices |

Appendix

Exhibit 1. The National Specified List of Susceptible Products (NABP, 2004)

1. Combivir® (lamivudine/zidovudine)
2. Crixivan® (indinavir)
3. Diflucan® (fluconazole)
4. Epivir® (lamivudine)
5. Epogen® (epoetin alfa)
6. Gamimune® (globulin, immune)
7. Gammagard® (globulin, immune)
8. Immune globulin
9. Lamisil® (terbinafine)
10. Lipitor® (atorvastatin)
11. Lupron® (leuprolide)
12. Neupogen® (filgrastim)
13. Nutropin AQ® (somatropin, E-coli derived)
14. Panglobulin® (globulin, immune)
15. Procrit® (epoetin alfa)
16. Retrovir® (zidovudine)
17. Risperdal® (risperidone)
18. Rocephin® (ceftriaxone)
19. Serostim® (somatropin, mammalian derived)
20. Sustiva® (efavirenz)
21. Trizivir® (abacavir/lamivudine/zidovudine)
22. Venoglobulin® (globulin, immune)
23. Viagra® (sildenafil)
24. Videx® (didanosine)
25. Viracept® (nelfinavir)
26. Viramune® (nevirapine)
27. Zerit® (stavudine)
28. Ziagen® (abacavir)
29. Zocor® (simvastatin)
30. Zofran® (ondansetron)
31. Zoladex® (goserelin)
32. Zyprexa® (olanzapine)

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