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ABSTRACT

Both nationally and internationally pharmaceutical counterfeiting has become a problem threatening economic stability and public health. The purpose of the present research study review was to analyze the scope and severity of pharmaceutical counterfeiting and to establish if the implantation of the Radio Frequency Identification Device (RFID) model can more efficiently be used within the pharmaceutical supply chain to reduce the problem counterfeit drugs impose on public health and international economic stability. Results indicated that implementing the RFID model for tracking drugs at the item-level in the pharmaceutical supply chain has potential to alleviate the scope of the counterfeit drug problem. Recommendations for how the pharmaceutical industry may sooner adopt the RFID model are made.

Key Words: Counterfeit drugs; RFID; FDA; supply chain; patient safety; pharmaceutical

INTRODUCTION

Counterfeit drugs are products which have been intentionally and fraudulently mislabeled with respect to their identity and/or source. They may and usually do have the same name as a brand name (or generic) drug however do not possess the same active ingredients or the correct dosage of ingredients. In some instances, the ingredients used in these counterfeit products have been toxic (Centers for Disease Control [CDC] 2009). The use of counterfeit medicines frequently results in treatment failure or death (WHO 2010) and represents a significant public health problem. For example, in Southeast Asia counterfeit drugs are considered one of several factors contributing to a growing resistance to anti-malaria drugs (Lon et al. 2006; Arguin et al. 2008; Dowell et al. 2008). Counterfeit anti-malaria medications may account for approximately 100,000 deaths annually in Southeast Asia (Global Health Forum 2009; Wyld 2008). In Nigeria, Africa, health officials estimate that 70% of the drugs in circulation are either counterfeit or adulterated (WHO 2006a).

While the problem of counterfeit drugs may be more pronounced in Less-Developed Countries (LDCs), the problem certainly is not limited to LDCs. Recently in 2007, the Royal Canadian Mounted Police found a retail outlet distributing counterfeit Norvasc®-labeled doses containing only talc, rather than the name-brand Norvasc® medicine, typically prescribed for cardiovascular disease. In 2004, investigators in the United Kingdom discovered counterfeit versions of the popular drugs Lipitor® (for cholesterol reduction); Cialis® (for erectile dysfunction); and Reducil® (for treatment of obesity; Deisingh 2005; Wyld 2008) being distributed to patients.

In wealthier nations, new expensive lifestyle medicines, such as hormones, steroids, antihistamines, and erectile dysfunction drugs, are significant targets for counterfeiting. For

instance, one of the most commonly counterfeited drugs in the United States is Viagra®. While the distribution of counterfeit products certainly poses a public health risk to wealthier countries, it does not present the potentially deadly implications that counterfeit drug distribution causes in LDCs. With less disposable income to spend on life saving drugs and none to spend on life style enhancing drugs, citizens of LDCs are more susceptible to the lack of effectiveness when receiving counterfeit drugs for life threatening conditions such as malaria, tuberculosis, and HIV/AIDS (Behrens 2002; Newton et al. 2006). The U.S. Food and Drug Administration (FDA) in 2004 reported counterfeit drugs to be endemic in some countries, where some patients have a greater probability of obtaining spurious medicines rather than authentic and reliable medicines.

The World Health Organization (WHO 2006b) has estimated that over 10% of all drugs in the supply chain worldwide are counterfeit. Tragically in some countries counterfeit drugs make up more than 30% of the drug supply. It is estimated that drugs purchased over the internet are counterfeited in about 50% of cases (WHO 2006b). Unfortunately, the severity of the problem is difficult to accurately assess, since counterfeiting is hard to detect, investigate, and quantify. In addition, inadequate legislation, regulation, and enforcement and the ineffective relationships between health authorities, customs agencies, police, and the pharmaceutical industry have contributed to the growth of the counterfeit drug market (International Medical Products Anti-Counterfeiting Taskforce [IMPACT] 2008). Pharmaceutical counterfeiting is a profitable market. The FDA (2005b) estimates that the counterfeit drug industry generated over $35 billion dollars in 2005. This figure has been predicted to increase to $75 billion annually during 2010 (Booz Allen Hamilton 2006). Just selling counterfeit drugs via the internet produces an estimated $15-$20 billion annually (Oliver 2000; Crawford 2003).

In the United States, Vastag (2003) and the FDA (2004) have estimated counterfeit drug sales account for one to five percent of the total drug sales. The combination of a huge market and the increasing demand for less expensive drugs suggests that in 2009 as many as 35,000 million prescriptions were filled with counterfeit drugs (Wyld 2009). The FDA International Medical Products Anti-Counterfeiting Taskforce (IMPACT) has been working with similar agencies in Europe, the Interpol, and the American private sector to help protect the U.S. drug supply from the cracks in the pharmaceutical supply chain leading to counterfeiting and to fight the threat presented to consumers by counterfeiters (FDA 2004; Young 2003, 2004a). In 2006, software and hardware companies had made encouraging progress toward implementing Radio Frequency Identification Devices (RFID) for ensuring the authenticity of drug products provided to consumers through retailers (FDA 2006).

RFID, a technology invented in the 1970s, uses radio waves to automatically identify people or objects (Becker, 2004). This technology provides an automatic identification method by relying on storing and remotely retrieving data using devices called RFID tags or RFID transponders (Bouchie 2003). The RFID tag is essentially a chip that can be attached to a variety of objects, including products, animals, or people. The radio waves RFID tags emit enable ongoing product identification (Young 2004b).

There are several methods for identifying products as authentic. The most common method has been serial numbers used to identify a person, object, or potentially other information on a microchip attached to an antenna. This data are then transmitted into a computer that can retrieve the data and match the item's serial number (Becker 2004; James 2005). In addition to its use in identifying counterfeit drugs, RFID has been employed in the health care industry in emergency rooms (Chen et. al. 2008), in operating rooms during surgery (Ratter 2004; Bacheldor

2007a, 2007b; Swedberg 2009), for anesthesia delivery (O'Connor 2004), with Alzheimer patients (Foster 2008), and by pharmaceutical companies for hospital supply chain management (Jusko 2007; Wyld 2008).

While RFID can be used to accomplish a multiple of objectives, the purpose of this study was to analyze the scope and severity of pharmaceutical counterfeiting and speculate on the application of the RFID model as a potential strategy for addressing the public health problem presented by pharmaceutical counterfeiting.

METHODOLOGY

It was conducted a comprehensive review of the literature concerning pharmaceutical counterfeiting and the role of RFID in stopping/reducing this problem. The search was limited to articles from quality journals for which the articles could be accessed using electronic databases. All researched topics related to the advantages and disadvantages of RFID technology to battle pharmaceutical counterfeiting. The research strategy yielded journal articles of high impact, and an analysis of findings from the literature was performed. The articles were investigated to determine their pertinent findings as stated or implied according to their general perspectives.

Search Strategy

When completing the search for articles, the following keyword terms were combined using the Boolean "OR": "counterfeit" OR "pharmaceutical" OR "medicine" OR "drug" AND "RFID." All pertinent articles came from four electronic databases including EbscoHost, Springer, *RFID Journal*, and Pub Med. Reference lists from retrieved articles were utilized to identify other relevant research articles. All articles written in languages other than English were excluded. The FDA and WHO websites served as important sources for gaining insight regarding the pharmaceutical counterfeiting situation at the national and international levels.

Inclusion, Exclusion, and Assessment

Even though abundant information regarding pharmaceutical counterfeiting is available we restricted this review of the literature to only those articles addressing RFID. Articles relating to the general history, legislative history, and future of pharmaceutical counterfeiting and to RFID chips and the use of RFID chips as a solution to drug counterfeiting were included in the analysis, while all other articles were excluded. Reviews and primary research articles were included in this study. All selected articles were in English. No published articles were excluded due date of publication, but we excluded all unpublished manuscripts. The total sample of articles included in this study was 24.

RESULTS

Across Southeast Asia, where the percentage of counterfeit drugs has been reported to be as high as 53% in some of its countries, anti-malarial drugs have been the most commonly counterfeited products (Lon et al. 2006; Arguin et al. 2008; Wyld 2008; Global Health Forum 2009). Scientists in Asia have been trying to combat counterfeit drug distribution by raising awareness of the problem among doctors and patients and by running lab tests to screen for counterfeiting (Aldhous 2005a; Dowel et al. 2008;). In 2006, China's State Food and Drug Administration closed 1,300 illegal factories and investigated cases of counterfeit drugs worth $57 U.S. million. In 2003, counterfeit drugs were estimated to represent between 15% and 20% of the domestic drug market in India, which was also valued as worth US one billion (Prakash 2009). Moreover, the distribution of counterfeit antiretroviral drugs for HIV/AIDS continues as a very serious, life threatening problem throughout Africa (WHO 2003; Amon 2008)**.**

In Europe, over 60% of the medicines purchased online are counterfeit and could potentially be lethal for vulnerable patients (European Alliance for Access to Safe Medicines

[EAASM] 2008). The EAASM (2008) adds that for over 100 online pharmacies selling 30 commonly purchased prescription-only medicines, 62% of the medicines are counterfeit and 95.6% of the pharmacies operate illegally. These astounding and high estimates for Europe provide an indication of the magnitude of counterfeiting worldwide, suggesting the problem may be out of control and growing day by day (Prakash 2009).

The quality, safety, and efficacy of both imported and locally manufactured medicines in many developing countries cannot be guaranteed (WHO 2006). Medicines exported from many industrialized countries to LDCs are not regulated to the same extent as medicines produced and distributed within a given nation, increasing the likelihood of counterfeit drugs being distributed worldwide (Frankish 2003). The overall lack of regulation and enforcement has intensified the counterfeit drug situation (Bouchie 2003; Ham 2003).

The Office of the U.S. Trade Representative (2002) relaxed patent restrictions to allow poorer and developing countries greater access to pharmaceuticals and test kits during public health crises. This plan was designed to increase access to needed drugs and to allow countries, such as India and Brazil, to manufacture generic versions of drugs patented in the U.S. for export to countries lacking domestic production capacity and to curb the HIV/AIDS epidemic. For example, drugs and test kits were sent to sub-Saharan Africa through this program (Office of U.S. Trade Representative 2002). While this strategy has increased access to drugs, it has also provided greater opportunities for producing counterfeit drugs. For example, most of Nigeria's counterfeit drugs originate in China and India (Raufu 2003; Aldhous 2005b; Cockburn et al. 2005). In India, the quantity of counterfeit drugs in circulation is so high that the parliament attempted to pass a bill authorizing the death penalty for medicine counterfeiters (Rudolph and Berstein 2004).

In the United States, the FDA (2004) estimates that counterfeit drugs account for approximately one percent of the prescription drug market. With over one billion pills being sold every year, that percent amounts to over one million counterfeit pills being consumed by Americans (Rudolph and Berstein 2004). In addition, the FDA screens less than one percent of drug products being sent through the U.S.'s domestic mail system. A study from the Pharmaceutical Security Institute (PSI 2008), a not-for-profit consortium of pharmaceutical companies dedicated to decreasing the counterfeiting of drugs, reports an increase in reported incidents of counterfeiting from 196 in 2002 to 1,834 in 2008, representing an increase in counterfeiting of over 900%. Congressional Representatives Steve Buyer (R) and Jim Matheson (D) estimate that 130 million counterfeit drug packages are sold annually in the U.S. As such, they introduced bipartisan legislation to protect U.S. society from counterfeit drugs through HR 5839: *Safeguarding America's Pharmaceuticals Act of 2008*. The bill was referred to the House Energy and Commerce Committee Health Subcommittee in 2008; however, the committee took no action on HR 5839. The bill died in committee and is expected to be reintroduced during a future congressional session. Issues related to regulatory cost and privacy were the major barriers inhibiting the bill from receiving a positive committee recommendation.

The U.S. faces a growing public health problem with counterfeit drugs infiltrating its legitimate drug supply chain and being sold at the full price commanded by legitimate drugs in retail pharmacies and hospitals (Scheckelhoff 2006). In the U.S., examples of counterfeit drugs found in the regular market include Lipitor® (for treatment of high cholesterol), Viagra® (for treatment of erectile dysfunction), Procrit® (for treatment of anemia), Zyprexa® (for treatment of schizophrenia) among others, and these drugs usually produce high volume and retail at a high cost (Rudolf and Berstein 2004). The FDA (2005b, 2006) has stepped up its efforts to improve

the safety and security of the national drug supply by encouraging companies to use electronic technology to tag product packaging. The FDA encourages the pharmaceutical industry to use this electronic pedigree, or "ePedigree," system to track drugs from factory to pharmacy. Such technology may prevent shipment diversions and counterfeiting of drugs because it can enable wholesalers and pharmacists to determine packaged drug products' identities and dosage throughout the entire supply chain (FDA 2005a, 2006). The FDA has been pushing the pharmaceutical industry to use solutions for generating a pedigree of history digitally through the ePedigree system (FDA 2005b Young 2004a). RFID represents a form of wireless identification, provides an effective tool for tracking moving objects throughout the manufacturing and shipping process, and lends itself readily to the ePedigree system. The RFID chips allow manufacturers and distributors more precise tracking of their drug products throughout the supply chain (Becker 2004).

Johnson & Johnson has emerged as a leader among pharmaceutical companies by establishing standards for RFID technology and participating in RFID pilot studies. The company currently employs RFID to comply with retailers' mandates that certain products be shipped with RFID tags. Johnson & Johnson has performed tests using RFID tags to track promotional display shipping and currently employs the technology with surgical implements (O'Connor 2008).

Other companies using RFID for tracking drugs include Pfizer, GlaxoSmithKline, and Purdue Pharma (FDA 2005b). Pfizer began tagging bottles of Viagra® for U.S. distribution with RFID prior to 2009. In actually, by 2006, Pfizer had already spent $5 million to implement RFID with Viagra® (Pfizer 2006). During recent years, other companies have advanced their pilot programs and expanded the use of RFID to encompass entire product lines. In addition, pressure

from the FDA has prompted the pharmaceutical industry to adopt RFID as a means to stop counterfeiting (Krohn 2005; FDA 2006).

A system-wide challenge faced by both pharmaceutical manufacturers and retailers involves determining the product custody at various levels along the supply chain. The complex pharmaceutical distribution infrastructure ensures difficultly in maintaining supply chain integrity as products move from the manufacturer to the point of sale (Texas Instruments [TI] 2005). Because of this complexity, Texas Instruments and VeriSign have partnered to develop the authenticated RFID model as a joint project. The partnership between VeriSign and TI has proven industry interest in combating pharmaceutical counterfeiting. The authenticated RFID model is expected to support item-level authentication from origin to the pharmacy as point of sale and at any point along the chain of custody between the beginning and end points in the distribution chain (TI 2005). RFID technology, such as the model developed by TI and VeriSign, can provide the exact location of any pharmaceutical product at any given place along the supply chain. In particular the TI-VeriSign product, as reported by TI (2005), features "Unique RFID Tags" with digital signing of tags and supply chain event validations.

According to the Healthcare Distribution Management Association's (HDMA) Healthcare Foundation, the benefits of RFID far outweigh the costs and can potentially save pharmaceutical manufacturers as much as one billion and healthcare distributors as much as $400 million (HDMA 2006). Additionally, implementing a RFID system could enable participants in the pharmaceutical supply chain the ability to assure their customers receive safe and authentic products, since the gaps in supply chain integrity could be lessened and companies' branding, reputations, and financial performance could be secured (FDA 2004).

RFID technology has become the leading candidate for the tracking the authenticity of drugs (McDonald 2008). A complete RFID serialization requires a costly infrastructure, and some pharmaceutical companies may not see the benefit, even though RFID has more advantages over other tracking options such as barcodes. RFID can hold more information, the scanning technology can quickly read the serial number of every bottle in a case, and RFID will be more difficult than barcodes to counterfeit (Young 2004b). Bar codes have not been the best technological solution to the counterfeiting problem and not always correctly identify objects and patients (McDonald 2008). Therefore, RFID may replace bar coding in the long term (McDonald 2008). RFID more effectively and easily ensures the authenticity of drugs. Further, a drug's ePedigree within the chain of custody from the point of manufacture to the point of sale and the integrity of the manufacture and distribution of the pharmaceutical product are maintained (Thompson 2004). Common use of ePedigree via RFID offers the opportunity to improve patient safety and to protect public health by allowing wholesalers and retailers to rapidly identify, quarantine, and report suspected counterfeit drugs and to enable efficient, targeted recalls (FDA 2006). Most of the benefits of RFID implementation are accomplished through securing the supply chain, improved accounting accuracy, and greater warehouse and inventory efficiency. The benefits increase as more products are tagged at the unit-of-sale level (Lee 2004; Young 2004b).

In 2004, the FDA optimistically looked toward rapidly developing RFID technology and ePedigree within the pharmaceutical industry to curb pharmaceutical counterfeiting problems. The FDA had high hopes that this data collecting technology would be ready for implementation by 2010 (FDA 2006). Despite the FDA's efforts, the failure of legislation introduced into the House of Representatives, and even with more advanced RFID implementation being available,

companies remain unprepared to use RFID tracking with pharmaceutical products throughout the entire drug distribution system (Young 2004b).

An examination of expert testimony provided to the House Committee on Energy and Commerce provides insight into the issues inhibiting the passage of pro-RFID legislation for combating counterfeit drugs. In 2004, Vice President and General Manager for Marketing and Sales, Americas, for Philips Semiconductors William Galione (2004) addressed the three critical obstacles to RFID: dollars, feasibility, and privacy. In his expert testimony, Galione predicted a 23% compound annual growth of RFID worldwide through 2007 and suggested that the cost savings amounted to approximately five percent of sales, a significant contributor to increasing profits. When responding to the privacy issue, Galione assured the House Committee that Philips Semiconductors was working with the private sector and government to address privacy concerns. In contrast, the Vice President and Head of Global Corporate Security Novartis International AG James Christian, when presenting expert testimony before the House Committee in 2005, questioned the value of RFID for battling counterfeit drugs. Christian (2005) contended that while RFID was suited to inventory management, RFID "missed the mark" as an anti-counterfeiting strategy. Christian communicated numerous concerns about RFID and primarily focused on packaging obstacles. Christian suggested that in almost every circumstance (RFID included), the technology enabled a company to track the cardboard containing the products and not the item-level products. Therefore, genuine products in counterfeit packages and counterfeit products in genuine packaging could minimize the value of the technology (Christian 2005). On the other hand, Galione (2004) addressed this packaging problem by arguing RFID technology could be used for item-level identification, since RFID could "see" through the packaging to identify specific items due to its use of radio signals rather than

barcodes. In reality, the differences in these two experts' perspectives have inhibited the advancement of RFID legislation designed to curtail the counterfeiting of drugs.

Privacy is another critical obstacle to passing legislation designed to promote the RFID model for battling counterfeit drugs. Associate Professor of Mechanical Engineering Massachusetts Institute of Technology Dr. Sanjay Sarma (2004), in expert testimony before the House Committee, indicated that subscribers to the EPCglobal Network have adopted guidelines for following international laws and regulations related to consumer privacy protections. However, during the same hearings, Staff Counsel Center for Democracy and Technology, Paula Bruening (2004) reported that RFID devices can be linked to personally identifiable information of consumers, hence raising significant privacy issues. Bruening later admitted the problems are not insurmountable but will slow the process of RFID acceptance. During the House Committee's hearings, Jan Schakowsky (D-IL; 2004), a member of the health subcommittee, contended that RFID can provide substantial benefits combating counterfeit drugs; however, Schakowsky was unwilling to sacrifice personal privacy and civil liberties in order to reduce counterfeiting with RFID. Since the legislation has not been moved out of committee over the five year period from 2004 to 2009, Schakowsky's concern likely represents a significant barrier to the success of the RFID model.

In order to achieve track and trace capabilities, all parts of the supply chain would have to invest in and utilize compatible RFID technology and would have to agree to capture and share information about product movement via the use of common data formats industry wide (Young 2004b). The high costs of implementing an industry-wide RFID infrastructure and the lack of industry standards presently prevent wide-scale adoption of the technology. Jones (2005) attributes the cost of using RFID to derive from three elements: (1) *Tag*, for which the costs

depend mainly on read range, chip usage (or chipless tracking), and the ability to rewrite (or dispose of) tags; (2) *Reader/writer*, for which the costs depend on complexity and power (low frequency equals less costly) of any reader/writer technology; (3) *System integration*, which represents the biggest cost at all levels of industry from the manufacturing through point of sale and depends on compatibility factors between standards and companies along the supply chain.

A critical mass of industry participation is required to lower the costs of RFID use, infrastructure, and robust industry-wide standards, yet such a critical mass will remain difficult to achieve unless implementation costs come down and large-scale, robust standards are implemented. Many companies and retailers are looking for a positive return on their investments (Krohn 2005). Since RFID development remains in an early stage, failure to see immediate monetary returns versus the cost of implementation presents a significant barrier and deters companies from implementing the technology. Jones (2005) describes additional barriers beyond the cost factor to implementing RFID involve resistance to change, established barcode infrastructure, lack of standards, and lack of skilled personnel. However, some progress has been made with Wal-Mart implementing RFID tags in its Dallas-Fort Worth, Texas stores (Thompson 2004; Weier 2008). Moreover, the manufacturer of OxyContin® has begun implementing RFID for shipping this theft-prone painkiller (Malykhina 2004).

DISCUSSION

A comprehensive review of the current literature leads to the conclusion that worldwide drug counterfeiting is a significant and growing public health problem. The WHO (2006a, 2006b) estimates that over 10% of the drugs sold worldwide are counterfeits. While that percentage is significant, the WHO cautions that drug counterfeiting is extremely difficult to estimate and emphasizes its estimate of 10% is conservative. As demonstrated previously, the problem of

counterfeit drugs is particularly acute in LDCs where the drugs needed are for combating life-threatening diseases such as malaria, HIV/AIDS, tuberculosis, and many more deadly diseases.

In addition to the medical and social problems associated with counterfeit drugs, the economic costs are considerable. Once again the numbers are only estimates; however, the cost worldwide exceeds $35 billion annually. Cohen and Hawkins (2007) argue that the counterfeit drug problem has become uncontrollable, partially due to corrupt governments experiencing financial gain by counterfeiting drugs. Christian (2005) called the countries of Russia and China "heaven" for counterfeit drug producers and distributors and indicated drug counterfeiting was substantially on the rise in Latin America. Since the reduction of trade barriers between countries has led to increased counterfeiting, consistent and systematic efforts are needed at the international level. These efforts should include the timely and appropriate exchange of information and measures such as RFID to curb or prevent the ongoing spread of counterfeit drugs (Cockburn 2005). Some countries have begun to make serious efforts to address the drug counterfeiting issue.

In the U.S., while well-developed legislation protecting the civil rights of individuals remains feasible and can contribute to stemming the flow of counterfeit drugs, in and of itself legislation will not be enough to solve the counterfeit drug problem. The bar coding of products has been used to track packages or pallets of products, but as was pointed out during House hearings (Gailone 2004; Sarma 2004), bar coding is limited to line of sight code reading which prevents item-level supply chain tracking. Meanwhile, RFID technology eliminates the physical and management problems associated with bar coding and enables item-level tracking. However, RFID technology remains expensive to implement. Adoption of RFID has grown slowly with a small number of hospitals and pharmaceutical companies implementing the technology. On a

positive note, Huang and Ku (2008) found that patient safety can be enhanced by RFID applications and RFID use reduces both costs and errors in operating and emergency rooms.

The use of RFID to defend against pharmaceutical counterfeiting is still in the early stage. Any evidence either for or against the RFID model was, as a result for this study, difficult to obtain. RFID is a tool that can help reduce the worldwide drug counterfeiting epidemic. RFID cannot definitively solve the drug counterfeiting problem. Governments need to be willing to develop strategies to reduce corruption and criminal activity. Government need to promote cooperation between regulatory authorities, police, customs services, and judiciaries in the effort to effectively control the legitimate drug market, the reduction of the presence of the counterfeit drug market, and drug regulation (Cockburn 2005; Liang and Mackey 2009).

Before RFID tags can be implemented on a large scale, several problems must be overcome. The first of these problems is the lack of standards in the pharmaceutical industry. Until industry members agree upon a uniform coding scheme for products, RFID technology will not be widely implemented. The second problem is RFID implementation cost. The data revealed the implementation of RFID chips is an expensive, while extensive, solution. Even though the cost of the tags and the readers for RFID technology has dropped over 80% in the last five years, the higher cost associated with RFID persists. Based on the data, many companies have not implement RFID for tracking pharmaceutical products due to cost. Therefore, bar codes have continued to be cost efficient for companies and widely used. However, once an industry-wide coding scheme for products is accepted, the large scale adoption of RFID should further reduce costs. The third problem for RFID adoption is privacy of consumers and corporations. As reported in the results, industry leaders are concerned about competitors gaining access to critical corporate information via the radio signal producing RFID technology. Additionally, both

government and special interest groups are concerned about the potential to violate individual civil rights if tracking through the end of point of sale becomes an industry standard once RFID technology is adopted.

The evidence available suggests more interest in and greater acceptance of RFID technology as an inventory management and marketing tool (e.g., Wal-Mart) than as a strategy for identifying and disabling distribution of counterfeit drugs. The FDA (2009) continues recommending low-level technology strategies, such as watermarking. Until the FDA mandates the implementation of a sophisticated electronic tracking system, it will not happen, as suggested by Yoshida (2007). Promising new state-level regulatory requirements, such as the Florida Pedigree Act, force healthcare companies to use RFID to capture essential information in validating the drug supply (UPS 2005) and bode well for the future of RFID, if the state-level models work according to the suggestions found in this paper. Ultimately, the counterfeit drug problem operates nationally and internationally at an epidemic level and requires regulatory attention from governments worldwide.

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