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ELECTRONIC TRACKING OF PRESCRIPTION DRUGS

WHY IS IT TAKING SO LONG?

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When the Food and Drug Administration's (FDA's) Counterfeit Drug Task Force issued its first report in 2004, a key component of the framework envisioned for improving the security of the U.S. drug supply chain was widespread industry adoption of electronic track and trace technology such as Electronic Product Code/Radio Frequency Identification (EPC/RFID).[1] Using this technology, a radio frequency tag containing essential data about a prescription drug in the form of an EPC (i.e., a compact "license plate" code that uniquely identifies an object in the supply chain), would allow those in the supply chain to create a "pedigree" by tracking the chain of custody of each unit of a prescription drug. Specifically, by linking each unit to a unique EPC, the drug could be tracked electronically through the supply chain from manufacturer to pharmacy. Drugs without such identifiers could be quickly recognized and investigated for removal from the supply chain.

The fundamental technology of RFID is relatively uncomplicated. A basic RFID system consists of three components: a) "passive" tags, each comprised of microchip and an antenna; b) a reader; and c) a host computer system and application software. Data is transferred via low-power radio waves between a tag and a reader, which are tuned to the same frequency.[2] The reader sends out a signal, which is received by all tags tuned to that frequency in the immediate area.[3] The tags, which can be attached to virtually anything, receive the signal with their antennas and "backscatter" their stored data (which can include many bits of information about an item, including serial number, configuration, date and time it traveled through a certain zone, etc.) to the reader.[4] The reader receives the tag's signal with its antenna, decodes it, and transfers it to the host computer system.[5]

The Counterfeit Drug Task Force issued its 2006 Update on June 8, 2006.[6] Part of the Update addressed regulations promulgated by FDA under the Prescription Drug Marketing Act (PDMA), imposing obligations on certain wholesalers to provide prescription drug pedigrees. These obligations have been repeatedly stayed by FDA.[7] Adoption of EPC/RFID would mean that wholesalers could provide electronic pedigrees (Epedigrees) rather than paper-based pedigrees, which would be costly, burdensome, and capable of having their integrity compromised.[8] FDA had thought that the prospect of lifting the stay in 2006 would be incentive enough so that RFID would be the industry standard by then.[9] In addition, FDA devoted a significant amount of internal resources to supporting industry efforts to facilitate prompt adoption of EPC/RFID by the end of 2006 deadline.[10]

Wal-Mart and the Department of Defense[11] also provided incentives for early adoption by ordering their largest pharmaceutical suppliers to tag their products with EPC/RFID.[12] Both FDA and the stakeholders who advised them

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turned out to be overly optimistic. Although there have been a number of pilot studies, estimates are that no more than 10 prescription drugs will be tagged with the EPC/RFID technology by the end of 2006.[13] While FDA is still expressing strong support for early industry adoption of EPC/RFID, the 2006 Update did not recommend mandating EPC/RFID but rather recommended allowing the stay on the pedigree requirements to expire on December 1, 2006.[14] Below we discuss some reasons why EPC/RFID has not been adopted along the timelines originally contemplated.

Lack of Technical Standards

New technologies cannot be deployed without first putting into place an appropriate superstructure. In the case of EPC/RFID, until very recently, a lack of a harmonized standard (i.e., the communications protocol between the RFID tag and reader) was a major factor in delaying the implementation of RFID, both in the United States and worldwide. In the not-too-distant past, RFID vendors had adopted various standards, such as Class 0 (64 or 96 bit read-only tags) and Class 1 (64 or 96 bit read-write tags), which led to vendor incompatibility, manufacturing capacity constraints, low tag-yield rates, and high tag costs.[15]

In order to address the implementation problems, in December 2004 EPCglobal, the most prominent developer of RFID standards, ratified its second generation (Gen 2) standard. Gen 2, which conforms to the radio regulations of the Federal Communications Commission (FCC) and many other regulatory agencies around the world, can accommodate at least 96 bits of information on an RFID tag, enable customization of content, and allow RFID tags to operate with any manufacturer's reader. EPCglobal submitted Gen 2 to the International Standards Organization (ISO) for certification as a worldwide standard in January 2005.[16] Eighteen months later, in July 2006, ISO finally approved Gen 2 as a global RFID standard.[17] ISO's approval of Gen 2 should help to speed the adoption of RFID as it will, among other things, enable supply-chain partners to encode data and read EPCs from RFID tags in a similar manner, so that they can share an interoperable and software infrastructure.[18]

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Privacy Concerns

Another issue that has slowed the implementation of RFID is the perceived lack of data security. If the identifying tag is still on the drug when it reaches the consumer, it is possible that an unauthorized person with an EPC/RFID reader might be able to read the information on the tag without the person knowing it—even though the drug is in someone's purse, backpack, pocket, or pharmacy bag. Potential abuse resulting from improper use of extremely personal information could be offset by ensuring that tagging only occurs down to the dispensing level, by repackaging tagged drugs in non-tagged bottles and/or by placing dispensed drugs in pharmacy bags that cannot be "read." All of these solutions could present additional privacy concerns.[19]

In addition, detaching the tags at the dispensing level removes some of the benefits of using EPC/RFID and potentially diminishes the attractiveness of the technology to FDA and industry. FDA would like the tags to stay on for recall or withdrawal purposes. Retaining the tags would also be useful to identify counterfeit drugs that get into the U.S. supply chain through the back door (e.g., nursing homes). Obtaining access to information about how consumers actually use their drugs could be potentially very useful for manufacturers as well as for recall purposes.[20]

Privacy advocates and others have been raising privacy concerns with industry, the federal government, and state legislators around the country for several years.[21] This has led to a myriad of privacy bills being introduced around the country, which in turn has led to reluctance by some manufacturers and other supply chain participants to implement RFID due to fears of lawsuits in the event that personal information is compromised.[22] A key concern is the bit capacity of EPCs, which enable the assignment of individual identifiers to tagged objects.[23] This means that RFID has the potential to collect a great deal of consumers' personal information in company databases, and those controlled by third parties. Hence, database security is a paramount concern in the matter of protecting individuals' data.[24]

The issue of RFID data security was considered by the Federal Trade Commission (FTC) in 2005. After

conducting an extensive workshop with participants from all areas of the RFID industry, the FTC decided that federal intervention in data privacy was unnecessary, and decided to take a "hands off" approach.[25] Rather, the FTC encouraged the industry to follow the privacy guidelines promulgated by EPCglobal.[26] One of these guidelines concerns database security, wherein EPCglobal urges companies to ensure that any data associated with EPC must be collected, used, and stored in a manner consistent with existing privacy laws.[27] This guideline further states that companies should publish information on their policies concerning retention, use, and protection of personally identifiable information associated with EPC use.[28]

The FTC's recommendations and the adoption of Gen 2 as a worldwide RFID standard have resulted in more and more companies pledging to voluntarily abide by the EPCglobal's privacy guidelines.[29] Gen 2 has secure encryption and authentication protocols, and EPCglobal has maintained that it will store EPC-related data on servers "beyond the firewalls of corporations, logistics providers, and retailers all around the globe."[30] EPCglobal's proactive approach to privacy will likely help to alleviate fears about RFID database security in the future.

Other New Technologies

Those who have technologies that can be used either together with EPC/RFID or as an alternative quickly responded to the opportunity posed by the urgent need to improve the integrity of the U.S. supply chain. In turn, FDA has recognized that, as desirable as EPC/RFID is from its point of view, it may not be the magic bullet that will destroy counterfeiting. Rather than relying solely on EPC/RFID, FDA has realized that it needs to encourage industry to layer many different technologies, both overt and covert, to discourage constantly innovating counterfeiters.[31]

A layered approach is a valuable anti-counterfeiting tool, because it allows for verifying different information at different places along the way to the consumer, e.g., some at the manufacturer, some in distribution, and some at the pharmacy.[32] Because different degrees of sophistication are needed for adequate protection at different points of vulnerability, a layered approach can include economical solutions such as tamper-resistant seals, security inks, two dimensional (2D) bar coding, and customized taggants (i.e., microscopic substances using unique numeric sequence in multiple color layer format), in addition to RFID.[33]

An effective layered anti-counterfeiting initiative could also include primary labels carrying RFID tags or a serialized 2D bar code to ensure track and trace capability, while cartons can carry color-shifting ink, and taggants, which can be read by proprietary readers. These measures can be applied on digitally produced labels and cartons, which allow end users to better manage carton inventories and change labels frequently. These measures also give companies a means to detect counterfeiting and replace counterfeit drugs with legitimate product before they get to the dispensing unit.[34]

New State Pedigree Laws

With the federal pedigree law stayed and re-stayed by FDA, absent a federal requirement on wholesalers to provide pedigrees, some states have stepped into the breach. Florida's pedigree requirements commenced in July of this year, with California's regulation becoming effective in January 2007.[35] Nevada and Virginia have also passed pedigree laws.[36] As these laws can be complied with using already existing alternatives to RFID, such as bar code technology, this may have slowed the race towards EPC/RFID.[37]

Serialization

In order for each drug to be tracked individually as it moves through the supply chain, it needs a unique identifier number. There is widespread agreement that the industry should use a single numbering convention to reduce costs and complexity.[38] However, controversy still exists as to whether the National Drug Code (NDC) number assigned to each prescription drug by FDA should appear on EPC/RFID tags because, if surreptitiously read by an unauthorized EPC/RFID reader, it could jeopardize the privacy of patients and potentially endanger the integrity of the supply system.

No Cost/Benefit Data

A significant part of the costs for implementing EPC/RFID would fall on manufacturers, for it is likely that they would be responsible for initially tagging and coding most drugs before they enter the supply chain. Distributors and pharmacies would also incur costs from configuring the antennas and readers at distribution centers and pharmacies so that they will be able to read all tagged pallets, cases, and individual bottles as they go through the loading docks.

Theoretically, use of EPC/RFID technology should have a favorable cost/benefit ratio if universally adopted. Trading partners could share data to support enhanced integrity of

the supply chain, improve inventory control, facilitate recalls, withdraw product with expired use dates, reduce warehouse labor costs, and improve deduction and claims accuracy. However, these efficiencies may not be achieved if the industry must support two technologies, such as EPC/RFID and 2D bar code.[39] A 2004 study commissioned by the Health Distributors Manufacturing Association estimated that pharmaceutical manufacturers stand to gain $500 million to $1 billion annually by adopting EPC/RFID technologies. For distributors, annual gains were estimated to be $200-$400 million. That must be balanced against the start-up costs for a large manufacturer for systems integration, hardware, tags, and data processing software, which were estimated to range between $15-$20 million. One-time costs for implementing EPC/RFID for a large distributor for systems integration, tags, and data processing software were estimated to range between $9-$20 million.[40] Large pharmacies are reportedly particularly concerned about start-up costs because, unlike manufacturers, they cannot pass them on to consumers because most of their prescription prices are established under negotiated contracts.[41]

Accuracy and Safety

Where to put the tag on a vial or bottle so that the EPC/RFID reader will capture 100% of the contents of a case or pallet is a challenge for industry. Wal-Mart, which plans to require EPC/RFID tags on all products, is reading 90-98 percent of individual cases (those not stacked on pallets) but only about 60 percent of cases stacked on pallets. This is because radio waves are not able to penetrate some products enough to reach the tags on cases in the middle of the pallet. While this level of accuracy may be acceptable to Wal-Mart for non-pharmaceutical products, it may not be acceptable to regulators enforcing an electronic track and trace pedigree law.[42] In addition, as the Compliance Policy Guide issued by FDA which permits pilot studies exempted biologics and protein drugs, no studies have been done to establish whether EPC/RFID technology might affect them.

Research still needs to be done on whether the EPC/RFID tags work accurately for these products, and whether the tags might affect the safety or efficacy of some biologics.[43] If EPC/RFID is not adopted for all prescription drug products, including tablets, injectables, and solutions, both in branded and generic form, industry may not see the efficiencies necessary to justify the significant start-up costs.[44] In addition, citing to medical researchers' questions about the long-term health effects of prolonged exposure to low levels of electromagnetic radiation, recommendations have been made that studies be conducted to determine the effect of EPC/RFID tags on those within reader range, such as warehouse employees and pharmacists.[45]

Rights to Confidential Data

If manufacturers are responsible for most of the EPC/RFID tagging, it likely will become necessary to share with manufacturers data that wholesalers have historically considered to be highly confidential, such as customer information, identity of products, and quantities sold. Distributors do not want to put manufacturers in a position of using this data to substitute direct sales to retailers from manufacturers for sales through wholesalers. Settling what confidential business information will be shared and what restrictions will be placed on its uses is an issue that wholesalers must address with manufacturers, at least those who provide extensive services to pharmacists in addition to product delivery.[46]

Conclusion

In light of the complexity of the new technology, as well as the complexity of issues that have arisen as a result of trying to implement EPC/RFID within such a short time period, it is not surprising that adoption is proceeding more slowly than FDA and its stakeholders might have wished. Notwithstanding the delay, the process appears to have been beneficial. The standards superstructure has been established and progress has been made on resolving some of the key issues causing delays in adoption such as privacy and data security concerns. Importantly, technologies have been identified that can be used either in lieu of EPC/RFID or in addition to EPC/RFID that may result in a flexible layering of protection against counterfeit prescription drugs in the U.S. supply chain that may be superior to EPC/RFID alone. Moving from a narrow product focused approach to a broader result oriented approach that contemplates a steady increase in availability of new types of anti-counterfeit technology over the years may put the FDA and industry in a better position to effectively thwart the constantly innovating counterfeiter than imposing EPC/RFID on a one-time basis.

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[1] 1 FDA, Combating Counterfeit Drugs - A Report of the Food and Drug Admin. (Feb. 18, 2004), http://www.fda.gov.oc/initiatives/counterfeit/report02_04.html.

[2] *See* RFID: Rapid Deployment and Regulatory Challenges, Ronald E. Quirk & Stacia J. Borrello, Venable LLP (2005) at 1-2.

[3] *Id.* at 2.

[4] *Id.*

[5] *Id.*

[6] Memorandum from Andrew von Eschenbach, M.D., Acting Commissioner of Food and Drugs, FDA, to Randall Lutter, Ph.D., Associate Commissioner for Policy and Planning at 1 (June 8, 2006) (on file with author), *available at* http://www.fda.gov/oc/initiatives/counterfeit/report6_06.pdf.

[7] FDA, Counterfeit Drugs Task Force Report: 2006 Update at 6 (2006), http:// www.fda.gov/oc/initiatives/counterfeit/report6_06.pdf. (PDMA (Public Law 100-293) was enacted on Apr. 22, 1988 and was modified by the Prescription Drug Amendments (PDA), Public Law 102-353, 106 Stat 941. These provisions established requirements relating to wholesale distribution of drug products).

[8] *Id.* at 16.

[9] *Id.* at 5.

[10] *See* FDA, Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs, Guidance for FDA Staff and Industry, Sec. 400.210 (Nov. 2004), http://www.fda.gov/oc/ initiatives/counterfeit/rfid_cpg.html. (Without listing all of the support FDA has given, for example, FDA issued this Compliance Policy Guide indicating how it would use its enforcement discretion with respect to industry studies on the feasibility of using EPC/RFID for prescription drugs). *See also* Remarks by Randall Lutter, Ph.D., Associate Commissioner, FDA, speech before NACDS/HDMA RFID Healthcare Adoption Summit (Nov. 14, 2005), http://www.fda.gov/oc/speeches/2005/ radiofrequencyid1114.html. (In addition to working with companies, which were conducting EPC/RFID studies, FDA staff members attended meetings of EPC Global, a company developing EPCs. FDA also formed a Working Group within FDA on EPC/RFID issues. FDA officials also served on an inter-governmental RFID council coordinated by the Department of Defense. In addition, FDA officials have spoken at various industry meetings).

[11] E. Wasserman, *Prescription for Pharmaceuticals*, RFID Journal, (May/June 2005), at 33. Accenture coordinated a pilot study beginning in Oct. 2003, which included manufacturers, distributors and retailers as well as the HDMA and the NACDS.

[12] *Id.* at 34. Wal-Mart required its top 100 suppliers to put UHF/EPC tags on pallets and cases beginning in Jan. 2005 and has set the goal of having all suppliers ship tagged pallets and cases by the end of 2006. *See also* Jonathan Collins, *Europe Finds Its Own Path to ROI*, RFID Journal, (Sept./Oct. 2005), at 14.

[13] David Sims, *RFID's Pharmaceutical Speed Bump*, TMCnet, (Feb. 06, 2006), http://news.tmcnet.com/news/2006/02/06/1346027.htm.

[14] Counterfeit Task Force Report Update 2006 *supra* note 6 at 6. FDA also followed a recommendation in its report that it issue guidance as to what its priorities would be in future as to prioritizing enforcement of the pedigree requirements by issuing a draft Compliance Policy Guide. Among the factors FDA will use in determining whether to deploy enforcement resources are: 1) High value of the drug in the U.S. market; 2) Prior indicators, e.g., incidents of counterfeiting or diversion; 3) Reasonable probability of diversion (for newly-approved drugs); and 4) Other violations of law by the wholesaler. *See* FDA, Draft Compliance Policy Guide 160.900, Prescription Drug Marketing Act - Pedigree Requirements under 21 CFR Part 203 (June 2006), http://www.fda.gov/oc/initiatives/counterfeit/cpg.html.

[15] *See* Quirk & Borrello, *supra* note 2, at 4.

[16] *See* Mary Catherine O'Connor, *The International Standards Organization has made EPCglobal's UHF Gen 2 Air-Interface Protocol a Part of its ICO/IEC 18000-6 Standard*, RFID Journal, (July 13, 2006).

[17] *Id.*

[18] *Id.*

[19] Statement on the Use of RFID on Pharmaceuticals by Katherine Albrecht, Founder and Director, CASPIAN Consumer Privacy, and Liz McIntyre, Communications Director, CASPIAN Consumer Privacy (on file with author), *available at* http://www.spychips.com. Pharmacists may not wish to be responsible for removing tags. The consumer may inadvertently be provided with a previously tagged bottle. Consumers may take the tagged medication out of the foil envelope, allowing it to be read by an unauthorized person.

[20] Counterfeit Drug Task Force Report 2006 Update *supra* note 6 at 18. If the identity of the customer is included in the tagged information and such details are passed up the supply chain, this could raise some serious issues under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), which are beyond the scope of this article.

[21] *See* Jonathan Collins, *FTC Asks RFID Users to Self-Regulate*, RFID Journal, (May 10, 2005), at 1.

[22] *See* Quirk & Borrello, *supra* note 2, at 6.

[23] *See Radio Frequency Identification: Applications and Implications for Consumers*, FTC (Mar. 2005) at 13.

[24] *Id.*

[25] *Id.* at 16.

[26] *Id.* at 17.

[27] *Id.*

[28] *Id.*

[29] *See, e.g., T3CI Privacy Statement* (2006) *available at* http://www.t3ci.com/privacy.html; *Systemedia Receives Qualification as a Gen 2 RFID Label Converter*, RFID Gazette, Feb. 23, 2006, *available at* http://www.rfidgazette.org/2006/02/systemedia_rece.html.

[30] *See* FTC, *supra* note 23, at 16.

[31] Speech of Scott Gottlieb, M.D., Deputy Commissioner for Medical and Scientific Affairs, FDA, to the Parenteral Drug Associations Pharmaceutical Counterfeiting Conference (Mar. 3, 2006), *available at* http://www.fda.gov/oc/speeches/pda0303.html.

[32] *See* Daniel W. Engles, Ph.D., *On Drug Pedigree and RFID in the Pharmaceutical Supply Chains: A Recommendation to the FDA*, Executive Summary, (Feb. 24, 2006) at 1, *available at* http://www.fda.gov/oc/meetings/rfid/Engels.ppt.

[33] *See* William Makely, *Counterfeiting Security and Brand Protection*, Food and Drug Packaging, (Mar. 2006), at 2.

[34] *See* Engles, *supra* note 32, at 2.

[35] *Id.*

[36] E. Wasserman, *Prescription for Pharmaceuticals*, RFID Journal, (May/June 2005), at 34.

[37] Stacy Lawrence, *Pharmaceutical RFID Adoption Stalls*, eWeek, (Feb. 10, 2006), http://www.eweek.com/article2/0,1895,1925510,OO.asp.

[38] Counterfeit Drug Task Force 2006 Update, *supra* note 6, at 13.

[39] Wasserman, *supra* note 11, at 33, 39.

[40] Healthcare Distribution Management Association, Adopting EPC in Healthcare: Costs and Benefits (Nov. 2004).

[41] Wasserman, *supra* note 11, at 39.

[42] Mark Roberti, *Wal-Mart Tackles Out-of-Stocks*, RFID Journal, (Mar./Apr. 2005), at 32.

[43] FDA, Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs, Guidance for FDA Staff and Industry, Sec. 400.210 (Nov. 2004) at 2, http://www.fda.gov/oc/ initiatives/counterfeit/rfid_cpg.html. In order to fill this gap, FDA has begun its own study to evaluate the potential impact of RFID on certain drugs and biologics. *See* Counterfeit Drug Task Force Report Update 2006, *supra* note 6, at 11.

[44] Wasserman, *supra* note 11, at 38.

[45] Statement on the Use of RFID on Pharmaceuticals, *supra* note 19, at 2.

[46] Wasserman, *supra* note 11, at 38.