

E-Pedigree's Evolution

Recent legislative initiatives, technological advances and the financial benefits of electronic pedigrees have engendered a new willingness by pharmaceutical companies to utilize RFID in their battles against counterfeit drugs.

March 5, 2007—Much has been written about the implementation delays of the Food and Drug Administration's (FDA) electronic pedigree (e-pedigree) program. More than three years after the FDA proposed a universal RFID-based e-pedigree, fewer than 10 types of prescription drugs are currently being tagged upon entering the supply chain. Factors attributed to this inauspicious initiation include costs, privacy and legal matters, and a lack of technical standards. The tide may soon turn, however, as recent legislative initiatives, technological advances and the industry's realization of the financial benefits of e-pedigrees have all resulted in a new willingness by drug companies to utilize RFID in their battles against faux pharmaceuticals.

In 2003, the FDA released a report recommending that pharmaceutical companies use RFID to create e-pedigrees for tracking prescription drugs as they are distributed into commerce. With a unit of drugs tagged at the manufacturer, and with RFID interrogators tracking that unit through the supply chain to the pharmacy, the authenticity of the product could be assured. Soon thereafter, the organization implemented pilot programs and publicly declared that by 2007, it would like to see U.S. drug companies implement RFID to track all prescription drugs at the unit level.

Still, in spite of the FDA's recommendation, drug companies were initially hesitant to deploy RFID-based e-pedigrees, citing a number of factors for their delays.

First and foremost was the up-front cost of RFID. Manufacturers incur expenses from tagging and coding drugs before they enter the supply chain, while distributors and pharmacies sustain additional costs from deploying RFID interrogators and antennas at distribution and retail points. With no immediate return on investment, drug companies were initially reluctant to invest in the infrastructure necessary to create an RFID-based e-pedigree.

Consumer privacy is another key issue. Drug companies have expressed concern that if RFID tags containing identifying information were still on the drugs when they were sold, the firms could be found liable if unauthorized individuals were to intercept personal information without the purchasers' knowledge. The electronic product code (EPC) in RFID tags contains substantial bit capacity, enabling the assignment of individual identifiers to RFID tags. RFID can collect a good deal of personal information on tags, and in company databases, so drug companies fear that information might be accessible to experienced computer hackers and other unscrupulous individuals.

Yet another reason is that until recently, there has been no harmonized RFID standard. In years past, RFID vendors adopted various standards, which led, among other things, to equipment incompatibility, a lack of interoperability and high overall costs and inefficiencies.

Additionally, some states have implemented their own drug-pedigree laws with different compliance

requirements—none of which requires RFID. California, Florida, Nevada and Virginia have each passed pedigree laws, for instance. Many drug companies are now avoiding the upfront costs of RFID by using less expensive alternatives, such as bar codes and paper, to comply with these laws.

In June 2006, in light of the drug companies' reluctance to implement e-pedigrees, the FDA released an updated drug counterfeiting report urging the industry to move quickly to implement RFID. The organization announced that effective January 2007, it would lift the stay on regulations related to the Prescription Drug Marketing Act of 1987 (PDMA) [see FDA Issues New Counterfeit Drug Task Force Report]. These regulations require smaller drug distributors to institute pedigrees (though not necessarily electronic), to track the chain of custody of prescription drugs moving through their distribution systems. Although the PDMA regulations do not mandate e-pedigrees, the FDA hoped lifting the stay would encourage drug companies to implement RFID, which is a much more efficient tracking technology than either bar codes or paper.

However, a federal court subsequently blocked the FDA's plan. In summer 2006, 10 pharmaceutical distributors filed suit against the FDA in the U.S. District Court for the Eastern District of New York, seeking to prevent the agency's lifting of the stay on the PDMA regulations. The plaintiffs claimed the FDA's pedigree rules were unconstitutional since they applied only to smaller distributors, not the three largest U.S. distributors, termed the "authorized distributors of record" (ADR).

The court agreed with the plaintiffs and, in late 2006, issued an injunction, effectively reinstating the stay on the pedigree rules [see U.S. Judge Issues Injunction Against Drug-Pedigree Rules]. Sources say the injunction is likely to stay in effect until the suit is ultimately resolved, which could take years.

Nonetheless, many legal experts expect the FDA's PDMA rules to be instituted eventually. Courts typically favor the government in cases such as this, that allege violations of the U.S. Constitution's "equal protection" and "due process" clauses when the rational basis test applies—i.e., the challenger must show that a law is not rationally related to a legitimate government interest. This is a high burden to place on a challenger, and the government often wins these kinds of cases.

Ultimately, Capitol Hill may mandate a universal e-pedigree. In 2006, the U.S. Senate and House of Representatives proposed companion bills, both entitled the Reducing Fraudulent and Imitation Drugs Act of 2006. These bills would require all prescription drugs to be tagged with RFID or similar technology to create an e-pedigree for tracking and tracing purposes. Both bills are currently pending in committees and are expected to be taken up again this year by the new congress.

In July 2006, the International Standards Organization (ISO) approved EPCglobal's second-generation Class 1 protocol standard for RFID devices operating in the UHF (860 to 960 MHz) band, as part of its ISO/IEC 18000-6 standard. EPCglobal has maintained that it will store data on servers beyond the firewalls of corporations, logistics providers and retailers all around the globe. The adoption of Gen 2 as a worldwide standard should go a long way toward driving down e-pedigree costs and protecting privacy.

Some large drug companies are now rethinking their initial resistance to implementing RFID. These companies have recently launched pilot programs for RFID-based e-pedigrees, based on the idea that a universally adopted RFID e-pedigree could have a favorable cost-benefit ratio because it would enable trading partners to share data, improve inventory control, facilitate recalls and withdraw products with expired use dates. These pilot programs are presently in their early stages, and at this point it is difficult to gauge their ultimate success.

RELATED_ARTICLES Although e-pedigree implementation is still young, the handwriting is already on the wall. More than 10 percent of the global pharmaceutical commerce is counterfeit, with sales of fake drugs passing \$40 billion last year. Without adequate safeguards, counterfeit drug sales could top \$75 billion by

2010.

Drug companies certainly acknowledge what these staggering figures are doing to their bottom lines, and are coming to realize that the cost of implementing effective RFID-based anticounterfeiting systems is miniscule compared to the financial damage caused by the ever-increasing torrent of counterfeit drugs. What's more, with Gen 2's adoption as a worldwide standard, at least one initial reason for failure to implement RFID no longer exists. Congress is very interested in protecting the public from the dangers of counterfeit drugs, and could well mandate an e-pedigree if the industry does not do so voluntarily. Consequently, drug companies' experimentations with RFID are likely to evolve into a universal e-pedigree sooner rather than later.

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