The E-Pedigree Stalemate

e U.S. drug industry has been looking at how to collect data for pedigrees—documents that verify the chain of custody of drugs as they move through the supply chain. Now all eyes are on the big manufacturers, distributors and pharmacies to see how they will comply with California’s drug pedigree law, which requires that companies maintain electronic records for all medications sold in the state as of Jan. 1, 2009.

The goal is for all pharmaceutical, biologic and over-the-counter medications to be traced to their point of origin to ensure that each unit sold is not counterfeit. What happens in California could determine what will happen in other states, such as Florida, which also has passed a pedigree law (Florida does not require electronic pedigrees).

A number of companies have conducted trials that prove RFID can be used to collect pedigree information (see E-Pedigree Pioneers), but drug manufacturers now appear to be moving toward using 2-D bar codes, which can also hold unique identification numbers. Under the California law, pedigrees must originate with manufacturers, so they have to create a way to uniquely identify doses of their product (Florida requires pedigrees that start with distributors). The 2-D bar codes are cheaper to print and apply to drugs than RFID tags, and manufacturers gain few internal benefits from applying transponders.

Cardinal Health, McKesson and other drug distributors prefer RFID to bar codes because they would not have to pay the cost of the tags. And while they'd need to make an up-front investment in the RFID infrastructure required to capture drug shipment data, there would be no increased labor costs. To collect serialized data with 2-D bar codes, wholesalers and distributors would need to employ armies of workers to pick up bottles of pills and vials of drugs to scan the bar codes.

Retailers prefer RFID to bar codes for the same reasons. On Nov. 29, 2007, Wal-Mart sent a letter to its drug suppliers (the retailer has pharmacies within its stores) saying it plans to be ready to handle products with serialized data by Oct. 1, 2008, to ensure that any issues could be addressed in time to meet the Jan. 1 deadline. The letter also listed "Wal-Mart's serialization requirements." For item identification, Electronic Product Codes should be "the primary data carrier," with 2-D bar codes for "backup redundancy." Case and pallet tagging should also be done with EPC as the primary data

carrier and standard linear bar codes as the backup. Wal-Mart did not say it was mandating the use of EPC tags to comply with the California law, but it did say: “If you plan on using something different from the [list] above, briefly explain how you plan to be compliant.”

Clearly, the two solutions—2-D bar codes and EPC tags—have specific reasons for appealing to different players in the supply chain, so companies within the supply chain are likely to tussle over which solution to adopt. If all distributors and retailers throw their support behind RFID, that could move the industry to adopt the technology, but so far retailers and distributors have been reluctant to take a strong stand in favor of RFID.

Other factors that could tip the scales toward RFID include:

• The cost of the tags falling to 1 cent or less (which is unlikely to happen unless there’s a breakthrough in printed electronics)

• Early tagging efforts showing benefits for manufacturers that offset the cost (this hasn’t been the case with trials so far)

• The U.S. Food and Drug Administration or state governments mandating the use of RFID (which is unlikely, since a mandate would face fierce opposition from the industry)

So, it’s unclear whether 2-D bar codes or RFID will gain widespread acceptance in the drug supply chain. For the near term, both 2-D bar codes and RFID will be deployed to comply with the California law, while the leading industry players try to come to a consensus on which technology to use. Stay tuned.

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