

Purdue Pharma to Run Pedigree Pilot

The prescription drug manufacturer will use RFID to track and authenticate bottles of OxyContin as they move through the supply chain—from factory to pharmacy.

By Elizabeth Wasserman

May 31, 2005—Prescription drug manufacturer Purdue Pharma is participating in a pilot to create what is reported to be the pharmaceutical industry's first electronic drug pedigree using RFID tags to match each bottle of a drug with a corresponding record detailing the drug's movement through the supply chain.

The pilot is designed to meet a growing number of state regulations intended to secure the flow of prescription drugs from manufacturers to distributors and on to pharmacies by providing a system of tracking and tracing medicines. Florida, California, Virginia, Nevada and Indiana already have such laws on the books, and a dozen or so other states are considering similar legislation. The U.S. Food and Drug Administration has encouraged the regulations in order to better protect the nation's drug supply chain from counterfeiting, tampering and theft.

Purdue Pharma, a privately held firm based in Stamford, Conn., is participating in the pilot in conjunction with technology suppliers Unisys, headquartered in Blue Bell, Pa., and SupplyScape, of Cambridge, Mass. The technology companies have spent weeks designing and installing the pedigree system, based on SupplyScape's E-Pedigree software and Unisys' ES7000 hardware platform, which will manage the large amounts of data generated by RFID tracking.

The first electronic pedigree will be created in July on Purdue's shipments of OxyContin, a popular painkiller. The RFID-tagged OxyContin and its accompanying electronic pedigree will be shipped to H.D. Smith of Springfield, Ill., the nation's seventh-largest drug wholesaler. H.D. Smith will receive the product, authenticate the pedigree information using digital signatures, certify the pedigree and make sure its serial number—the Electronic Product Code (EPC) number—for each bottle of medication matches the corresponding EPC on the bottle's RFID tag.

"There are really two things this pilot accomplishes," says Todd Skrinar, a partner in Unisys' healthcare and life sciences practice. "One will be to enable a significant increase in patient safety by flagging possible threats to the supply chain. [The other] is that it will begin to set the stage for supply chain efficiency, as there is more clear exchange of information between trading partners."

Shabbir Dahod, president and CEO of SupplyScape, says the electronic pedigree document is designed to comply with the laws in each of the five states that have enacted pedigree legislation. Those laws all require the following data to be contained in the pedigree: the manufacturer's name, the product name, the item's lot number and expiration date, the location from which it was shipped and the facility to which it was sent. Each time the pharmaceutical item changes hands from a manufacturer to a distributor, wholesaler or pharmacy, information must be added to the pedigree to document the chain of custody.

The first of the state laws goes into effect in Florida on July 1, 2006. Up to this point, drug companies have

been unsure how to comply. One option involves labor-intensive, timely and potentially error-prone paper pedigrees. Dahod claims that the electronic pedigree process provides faster and more accurate verification and authentication and, at the same time, is less prone to human error. "We're integrating the pedigree process inside their business," says Dahod. "Now you have a real integration of the pedigree business process inside the full myriad of other business processes already occurring in these entities, and it occurs in a way that is integrated with ERP systems, WMS and RFID systems."

According to Dahod, when Purdue is preparing to send a shipment of OxyContin to H.D. Smith, the company's RFID system reads the tags on the bottles and feeds that information into SupplyScape's pedigree application. This application sends the pedigree to H.D. Smith, and the OxyContin is shipped to that company. After H.D. Smith receives the pedigree, the firm will authenticate it with digital signatures, then match it to the shipment of OxyContin by reading each bottle's RFID tag, Dahod says. If there are any discrepancies, the pedigree application immediately notifies workers at H.D. Smith.

The electronic pedigree system is designed to prevent altered or counterfeit drugs from entering the supply chain. Purdue made history in November 2004 by becoming the first drugmaker to integrate the RFID tagging of individual bottles of pills into a packaging line (see [Purdue Pharma Tags OxyContin](#)). At the time, one of Purdue's largest customers, Wal-Mart, had mandated that drug manufacturers start putting an RFID tag on each bottle of Schedule II narcotics destined for Wal-Mart pharmacies.

Since 1987, the FDA has been urging the pharmaceutical industry to better ensure consumer safety by limiting the drug supply chain's vulnerability to counterfeiting. But the push accelerated in 2003 after several high-profile cases of counterfeiting—including the watering down of the anticancer drug, Procrit, and the recall of the nation's most popular cholesterol-fighting medicine, Lipitor—after fake pills were confiscated by authorities. State lawmakers hope that the drug pedigrees will help ensure that, as medicines change hands in the supply chain, their authenticity will be certified so that consumers get the real thing. Each company in a supply chain for a particular drug shipment adds its own information to the pedigree, certifies the pedigree and transmits it to trading partners, who go on to authenticate and match it with the drugs being shipped.

Purdue Pharma officials say the electronic pedigree was a business process that fit in nicely with the work the company has done with RFID. The company has RFID-tagged and shipped more than 200,000 bottles of OxyContin since last November, and in January it started tagging bottles of a second pain medication, Palladone. Although Purdue says it hasn't seen its products mass-counterfeited like some other company's drugs, it notes that there were a few cases in 2001 where authorities confiscated some fake OxyContin. The company started its pedigree pilot out of concern for securing its supply chain and making sure consumers get authentic medications.

"It is really a natural extension of our RFID pilot," says Aaron Graham, Purdue Pharma's vice president and chief security officer. "Our very first concern is patient safety. But it will also help us satisfy the most progressive legislation we see—the requirement of the electronic pedigree."

Unisys' Skrinar says that the current plan is to monitor OxyContin's supply chain for 60 to 90 days in the electronic pedigree pilot. After that time, the companies will evaluate the results and develop a roadmap for moving forward.