



## **Pedigree Programs are Settling In**

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### ***Ahead of about-to-be-announced FDA rules, state programs are changing the distribution marketplace***

That giant sucking sound you might be hearing is the flow of more and more wholesale marketing of pharmaceuticals leaving the small, regional players, and going to the top five or ten companies led, of course by the Big Three, Amerisource-Bergen, Cardinal Health and McKesson. One of the main reasons for this occurring at this time is the imposition of pedigree rules by several states, with more to follow. There are likely to be variations of how pedigree rules are administered from state to state, even after FDA comes out later this fall with specific pedigree rules, as it indicated it would do when its Counterfeit Drug Task Force issued its latest report in June.

Reports are beginning to come in from several states as to how their programs are impacting drug wholesaling and distribution. As it imposed tough new licensing requirements, Florida found that the number of wholesalers who would continue to do business in the state dropped from over 1500 to around 1000. In Nevada, nearly half of the state's 470 or so exited the business, with around 200 no longer licensed, said Louis Ling, general counsel for the Nevada Board of Pharmacy, at the Pharma Trax meeting (McClean, VA; Aug. 7-9). In Indiana, the requirement of having either the Verified Authorized Wholesale Distributor (VAWD) certification from the National Boards of Pharmacy (Mt. Prospect, IL) or an "alternative" accreditation (none of which has been chosen as yet).

Meanwhile, pedigree compliance systems are being installed at a growing number of wholesalers. Some manufacturers (who, with the exception of California, have been excluded from pedigree rules), seeing the writing on the wall, are evaluating various commercial pedigree-software systems, or looking at alternatives. (However, the California legislature has passed a postponement of California's pedigree rules to 2009; California's program was one of the few that required pedigree documentation to be performed electronically from the outset.)

The state rules are energizing efforts to develop standards for data structures, digital signatures and RFID technology, if only because supply chain managers are uncomfortable dealing with paper pedigrees, notes Jeff Lovett, director of product management at networking giant VeriSign (Dulles, VA). "Florida is providing solid experience on the cost of moving large volumes of paper around," he says. "We've noticed a bigger push for looking beyond the document model of track-and-trace networks."

### **Squeezing secondary markets**

To a large extent, these developments are exactly what the pedigree laws were intended for: to drive out diverted sources of pharmaceuticals, to raise the bar on the business practices and professionalism of wholesalers, and ultimately, to secure the pharmaceutical supply chain. On the business, as opposed to regulatory, side, numerous small or specialty wholesalers are complaining that they are being arbitrarily excluded from the marketplace by their elimination from "authorized distributor of record" (ADR) relationships with manufacturers. An ADR does not need to comply with pedigree documentation rules, which are not applied when a pharmaceutical moves in the so-called "normal chain of distribution" from manufacturer, to wholesaler, to retail pharmacy or healthcare facility.

A number of "independent" wholesalers are banding together to try to address their own situation, as the National Coalition of Pharmaceutical Distributors (see p. 9). One wholesaler, RxUSA (Port Washington, NY), has filed suit against a number of wholesalers and manufacturers (Pharmaceutical Commerce, July/August, p. 6), is trying to get a class-action suit started against FDA, HDMA and others.

At the same time, there are unsubstantiated reports, from a variety of sources, that non-pedigreed secondary wholesaling, or sales of products diverted from one distribution channel to another, are continuing. It is said that some GPOs or healthcare systems are marketing their excess inventory to secondary wholesalers, and that there is growing trade between wholesalers in Puerto Rico, where no pedigree rules are in place, and mainland United States, with the effect of "washing" a pharmaceutical's pedigree so that it can enter the distribution system as if it were direct from a manufacturer. (It is worth emphasizing here that secondary wholesaling is not illegal, nor is moving product from one channel to another.)

### **IT opportunity**

Even though the bulk of pharmaceutical distribution, coming through the largest wholesalers who have ADR status, are not required to provide pedigrees, most of them have some system in place, if only to provide paper documentation. Many manufacturers, expecting that being involved in pedigree rules might be a good business practice in addition to a potential regulatory requirement, are looking at systems development.

To get these systems running, most of the industry is turning to a handful of software vendors. The apparent leader, at least in number of site implementations, is SupplyScape (Woburn, MA). Its software system is in use at HD Smith (Springfield, IL) where it has been installed at the company's Pompano Beach, FL distribution center, and will go live at several other HD Smith facilities in the near future. SupplyScape has also been deployed by FFF Enterprises (Temecula, CA), as part of its "Guaranteed Channel Integrity" program. And when Pfizer launched its RFID pilot program in January, it was revealed that SupplyScape is providing a pedigree-like functionality that enables RFID data to be collected from production, and then displayed to pharmacists or end users who wanted to verify the provenance of the Viagra product they were dispensing.

McKesson (San Francisco) has deployed the e-pedigree application of Axway (formerly Cyclone Commerce, Scottsdale, AZ) at its distribution centers, and has an ongoing effort with Axway as it continues an RFID program called OnTrack, in which tagged products are being scanned, and the data transmitted, through its supply chain.

Cardinal Health has just concluded an RFID program involving its packaging division, its distribution division, and several retail pharmacies, testing RFID technology and how well pedigree information can be processed electronically. VeriSign (Dulles, VA) was the IT vendor for the pedigree component of this program.

### **New players**

New entrants into the pedigree-technology space include 3i Infotech, (Mumbai, India, with U.S. offices in Edison, NJ), Raining Data (Irvine, CA), and ePedigreeNet, Inc. (Santa Clara, CA). 3i Infotech has an e-business platform called Orion, and has applications in reimbursement management, patient management, and pharmaceutical manufacturing formulation. The Orion Pedigree application is modular, says Sharad Vajpayee, a manager at the firm, and can be used with a variety of enterprise software systems.

Raining Data has had an e-pedigree solution since late last year, and has scored a customer win with Southwood Pharmaceuticals (Lake Forest, CA), which repackages pharmaceuticals for dispensing in clinical offices. Raining Data is also a contender in the RFID-tagging market, and emphasizes its use of XML communication standards to provide interoperability with IT systems. "Our flexible solution enables Southwood to seamlessly collaborate with their broad base of trading partners who have a varying degree of technical sophistication ranging from paper to electronic pedigrees transmitted via fax, email, ftp, AS2 and web services and handle non-serialized and RFID-enabled pedigrees," says Varun Gupta, product manager at Raining Data.

ePedigreeNet, which incorporated just over a year ago, is aiming to set up a hosted service that could be used by any trading partners, according to Tom Ku, president. "We don't think point-to-point solutions like those of our competitors are the answer that the industry needs," he says. He points to the structure of how the credit-card and banking industry has been able to develop a networked approach that permits individual retailers, banks and credit-card companies to communicate necessary information, but without revealing any proprietary information that is not necessary for a transaction.

"The current setup, with some traders being required to produce pedigrees, and others saying, in effect, 'trust me,' will not be sustainable," he says. A triangle of trading partners—the retailer, the manufacturer and the distributor—can intersect at this hosted service to quickly validate a shipment, or update its status. The schema would make use of the definitions that are currently being developed for RFID by EPCglobal (Princeton, NJ), and would be offered by a hosted data provider that ePedigreeNet will contract with.

It remains to be seen whether FDA, having lifted the stay on PDMA rules for pedigree—but extending the ADR logic into the national arena—will later require all distributors (and all manufacturers) to provide pedigree documentation. In the meantime, manufacturers themselves may seek better pedigree processes as part of securing the integrity of their own products.

"Manufacturers will not be given a free pass on pedigree," says Todd Appelbaum, a partner at Maxiom Group (Boston), a management consulting firm specializing in biotech start-ups. "Effective supply chain management does not start in the middle of the supply chain; it has to start at the beginning." In addition, says Appelbaum, biotechs will need to prepare for a variety of distribution models—conventional wholesale/distribution, specialty channels, direct distribution to clinics and so on. Track-and-trace capabilities might be important in many of these channels.

To prepare for the eventuality of pedigree, Appelbaum says, biotech execs should: become familiar with pedigree laws; monitor evolving regulatory requirements; start some sort of unit-level serialization planning—not necessarily based on the arrival of RFID. "Saying that RFID is not ready for commercial use is too convenient a way of avoiding planning," he stresses.

VeriSign's Lovett says that pedigree is just one part of a broader business requirement for brand security. "Data structure standards, digital signatures, RFID developments—these are all being driven by more than regulatory requirements. Several serialization projects that we're aware of are to demonstrate the value of managing supply chains with retailers." Some manufacturers with OTC product lines see the value of retail data, he says, and want to accomplish the same objectives for their ethical product.