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SPECIAL REPORT

Beating the e-Pedigree deadline

Published in *Packaging World Magazine*, June 2008, p. 63
Written by Steve Barlas, Contributing Editor

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FEATURE *The January 2009 e-Pedigree deadline set by California may have been pushed back two years, but that didn't stop Biogen Idec from forging ahead with a solution.*

The March 25 decision by the California Board of Pharmacy to push back the state's e-Pedigree deadline by two years (its second two-year delay) gives the overwhelming majority of the pharmaceutical companies in the U.S. new breathing room to meet the anti-counterfeiting measures laid out by the Golden State. But those same foot-draggers, who pushed first in 2005 for an e-Pedigree delay to January 1, 2009, and again for another delay to January 1, 2011, now are at risk for being awarded the Black Hat worn by bad guys. That allows the very small handful of companies who have solved the packaging serialization puzzle to claim the competitive and public relations benefits that come to those who wear the White Hats.



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A number of the members of the California Pharmacy Board complained at the March 25 meeting in San Diego about the continued niggling by large and small pharmaceutical companies who have continued to complain about the technological complexities of packaging serialization, supply chain integration, and pharmacy authentication. "All I'm getting is "We can't do it, we can't do it, it's too expensive," said a board member, D.

Timothy Dazé, deputy city attorney in Los Angeles. "And I ask, "What value do you folks put on a life?" Pfizer, for instance, has told the board it would take five to seven years to put serial numbers on all its products.

Of course, what has been lost amid the gloom and doom forecasts about what might have happened come January 1, 2009 in California if the e-Pedigree deadline were not lifted—drugs suddenly disappearing from pharmacy shelves!—is the very real progress in implementing track-and-trace technology, both with regard to 2D bar codes and radio frequency identification (RFID) tags. In January, for example, Cambridge, MA-based Biogen Idec announced it would meet the January 1, 2009 deadline for both of its high-value multiple-sclerosis products, Avonex and Tysabri. Each package will get a serialized, 2D data matrix bar code on the packaging line at Catalent Pharma Solutions, Inc.'s Philadelphia packaging facility where two dedicated lines have been equipped with bar code printing and packaging aggregation technology sold by **Secure Symbology**, (SSI) Inc. (www.securesymbology.com).

Smaller companies like Biogen Idec with limited product lines will obviously have to go to a contract packager with turnkey capabilities. So far, there seem to be only two options. SSI and Catalent, joined by e-Pedigree software vendor **rXcel Corp.** (www.rfxcel.com), are now offering a soup-to-nuts California implementation package. (Biogen Idec, however, is using SupplyScape's e-Pedigree software.)

SupplyScape (www.supplyscape.com), **rXcel Corporation**, and **Axway** (www.axway.com) are all certified by EPCglobal for their e-Pedigree systems. The only real rival to the Catalent/SSI/rXcel triumvirate is the conglomeration that calls itself "California Express." It is composed of SupplyScape, **Nosco** (www.nosco.com), and **Systech International** (www.systech-tips.com).

In terms of the larger manufacturers, of course, some, even some of the loudest California complainers such as Pfizer, have already stuck their toe in the water. Pfizer's RFID tagging of Viagra coming out of its French manufacturing facility has been well covered. So has Purdue Pharma's tagging of OxyContin. In fact, Purdue has attempted to resolve the conundrum faced by pharmaceutical companies using

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RFID, who have uniformly decided to use UHF tags on cases and pallets but have been unable to get even Gen2 tags to read well on item-level packaging, especially liquids. They could use HF tags on individual packages, where read rates are somewhat better, except the application of those tags slows down a packaging line considerably.

Purdue Pharma has apparently solved this dilemma by using near-field UHF tags on OxyContin, according to one source. James Hein, a company spokesman, was unable to comment. Near-field UHF involves putting a custom antenna on a UHF Gen 2 tag so it gets the best benefits of an HF and UHF tag. With a very simple antenna printable at high speed, this will be the cheapest EPC tag. If near-field UHF lives up to its promise and its limitations—specifically, high interrogator cost—are overcome, we may see it being used on a lot of items. For the time being, however, 2D bar codes are the serialization choice at the package level, and Biogen Idec may be the first company to cross the California compliance line. "Biogen Idec is the first company to publicly announce item-level serialization for its entire product line," says Kamal Mustafa, president of SSI, the company that is providing the bar code printing, product aggregation, and database operations installed at Catalent's Philadelphia commercial packaging facility, where both Avonex and Tysabri are packaged. It is that serialization of each item-level package that is the expensive part of the California e-Pedigree requirement. It makes past packaging operations, where only the lot number and expiration date were printed in a big linear bar code, look like horse and buggy days. Once the serialization is done, creating and integrating the e-Pedigree down the distribution line, and authenticating it, is the harder part of the process.

In a sense, compliance with California will be easier for Biogen than for many other companies. First, the company has only two major products; both Avonex and Tysabri are approved for multiple sclerosis. Pfizer, GlaxoSmithKline, and many of the other bigger companies have many more products, and the complexities of compliance with California by 1/1/09 were momentous.

The first decision Biogen had to make was whether it was going to use RFID tags or bar codes to carry the serialization numbers for each product. The RFID tags are much more expensive, costing 7-25 cents per label, depending on volume. A 2D bar code costs less than a penny to print. The big wholesalers such as Cardinal, Amerisource Bergen, and McKesson have all made it clear that they want drug manufacturers to put RFID tags on products. That's because if products are serialized with 2D bar codes, the wholesalers will have to open every carton and read every package—with a bar code reader—individually. That will take an incredible amount of time. RFID tags can be read by readers through the carton.

"While we strongly prefer that manufacturers embrace RFID because it offers the most efficient solution, we are willing to work with those who roll out 2D bar code serialization as an interim step," explains Barbara Brungess, director, corporate & investor relations, Amerisource Bergen. "This is especially true for biotech manufacturers as the industry still awaits the results of studies conducted by the FDA to determine what effect if any the scanning and reading of RFID tags has on biological products."

"RFID is the ultimate solution," states Biogen's Bob Hamm, executive vice president, pharmaceutical operations & technology. "However, it is still unproven where biologics are concerned. We opted for 2D bar codes based on the information available when we were designing our solution."

The job of working with Biogen's vendors and navigating the technical challenges of applying smaller, 2D bar codes to Tysabri and Avonex packages fell to Larry Singer, director, global supply chain at Biogen Idec. "2D bar codes are not a new technology," explains Singer. "What is new is adopting it onto a package." But that didn't turn out to be too big a problem. "You can get an extremely large amount of information onto a small label footprint when you use a 2D bar code," says Singer. "There is plenty of available real estate on the label. And as long as you are able to phase out your old product labels, there really isn't any additional cost to designing the new labels."

The major cost for Biogen is for the use of the SSI technology installed on the Catalent packaging line, and for the validation of the new packaging process once it is completed. SSI's Mustafa says each packaging line has slightly different requirements, and neither he nor Biogen's Hamm would discuss specific costs. But Mustafa says the cost of installing his "modules"—and there are three on the Biogen lines—can run anywhere from \$100,000-\$400,000. In Biogen's case, it is paying an incremental additional cost for every carton of product printed with a 2D bar code on the Catalent line, an incremental cost which basically reflects SSI's capital costs.

Because of its early start, Biogen Idec will have its feet up come January 1, 2009 just as nearly every other pharmaceutical company in the U.S. starts to sweat the Golden State's new January 1, 2011 e-Pedigree deadline. "We'll be done easy by 2009," states Mustafa. "With our eyes closed."

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