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Pharma Ponders a Track-and-Trace System

Last week, I was invited to speak at the RFID Track and Trace Health Care Summit, held each year by the Health Care Distribution Management Association and the National Association of Chain Drug Stores. The pharmaceutical industry drew a collective sigh of relief when California decided to

delay its pedigree requirements until 2015, so I was encouraged to see that some in the industry are still interested in exploring RFID's potential to capture electronic pedigree data automatically—until I realized most aren't.

Jeffrey E. Shuren, associate commissioner for policy and planning at the U.S. Food and Drug Administration (FDA), said the agency believes “the existing supply chain safety system for FDA-regulated products is not adequate,” and that there needs to be “a paradigm shift in supply chain safety.” The role of electronic track and trace will be critical, he told attendees. The U.S. Congress requires the FDA to publish guidelines in March 2010, and according to Shuren, there is continued activity in Congress that could require the agency to take a more proactive role in establishing track-and-trace requirements.



Paul Rudolf, a former FDA official and now a senior health-care advisor for law firm Arnold & Porter LLP, said he believes other states will follow California's lead and essentially enact pedigree laws with a similar timetable. California is requiring drug manufacturers to have e-pedigrees for half of their individual drugs by Jan. 1, 2015, and the other half by Jan. 1, 2016. Distributors must begin tracking with e-pedigrees by July 2006, and pharmacies one year after that.

Rudolf's argument was that since California had spent a great deal of time and energy over the past 12 months building a consensus among drug manufacturers, distributors and

retailers, it would make no sense for other states to begin all over again with industry meetings and hearings. Like California, most states won't require radio frequency identification, though that will likely be the most cost-effective way to collect e-pedigree data on individual units of drugs, because scanning bar codes on each unit would be too costly.

At the meeting, I got the feeling many attendees were there to hear the latest regarding which regulation is in the offing, and that they were happy to learn that no regulation is imminent. There was little discussion of the potential business benefits of employing RFID and 2-D bar codes for track and trace. I would have thought CEOs of large drug companies would be deeply concerned about what could happen if, for instance, 50 people were to die from taking counterfeit versions of their drugs. What would be the impact on their brand, and how would they reassure the public that the pharma supply chain is safe? It seems they're assuming that will never happen, and I hope it doesn't—but the possibility remains, especially given what's happening with goods coming from China.

In addition, you would think wealthy drug companies would be interested in using RFID to track the chemicals they receive into inventory for manufacturing, achieve inventory visibility, improve order accuracy, confirm delivery upon receipt and gain needed efficiencies in executing drug recalls. I heard no talk about any of these benefits (though I didn't attend every session, or stay for the second day).

I attended a panel discussion with representatives from two of the largest drug distributors: Ron Bone, senior VP of distribution support for McKesson, and Heather Zenk, director of integrated solutions for AmerisourceBergen. Bone made what I thought was the key point of the event: If the industry takes the five-year delay as a reason to stop its work involving RFID and track and trace, regulators will step in

and tell the industry what it should be doing. The FDA and state governments won't accept the excuse that drug companies can't meet pedigree requirements in 2015.

The challenge for the pharmaceutical industry is that utilizing RFID for track and trace requires sophisticated systems that can capture data about individual bottles with 100 percent accuracy. That is possible, but it will require improvements in the technology, as well as changes in the packaging. More than one speaker said they could read every tag on 60 bottles in a case, but once they went over that number, reliability began to decrease—with both high-frequency and ultrahigh-frequency systems.

We've seen RFID systems improve dramatically over the past two years. Certainly, if the drug companies work with the vendor community to develop products, they can achieve the 100 percent read rates required for e-pedigree. But it won't happen if the industry sees the five-year delay in pedigree requirements as an excuse to do nothing. And the industry will certainly lose the public's trust if people get sick or die from counterfeit drugs. I encourage the industry to heed Bone's warning: Keep working toward a system that is reliable, protects the public and guards companies from a potential public relations crisis.

Mark Roberti is the founder and editor of RFID Journal. If you would like to comment on this article, click on the link below. To read more of Mark's opinions, visit the RFID Journal Blog or click here.



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