Industry Opinion Favors RFID for Drug E-pedigree

With public comments in from about 55 sources, the U.S. Food and Drug Administration (FDA) is now proceeding to prepare a recommendation for an electronic pedigree (e-pedigree) system that pharmaceutical makers, distributors and retailers would required to use to identify products as they moved through the

supply chain. The track-and-trace solution would be used to not only record which parties handled a drug during shipment, but also verify its authenticity and thwart counterfeiting. The FDA was accepting public comment until May 19, and now it will begin the process of analyzing those comments before making its recommendation as to how drugs would be tracked, what technology and what standards might be used, and who could help create those standards. A spokesperson for the FDA says the agency is still reviewing the responses and could not yet comment on the agency's next step.

In 2007, the U.S. Congress passed the Food and Drug Administration Amendment Act (FDAAA), mandating the FDA to evaluate potential e-pedigree systems and based on that evaluation, to make recommendation by January 2010 (see All Eyes on FDA for Drug E-pedigree). To help guide it in this endeavor, the FDA asked the public which technologies are the most appropriate for a pedigree system, what their strengths and limitations are, how interoperable they are, what standards are necessary and what is the development were of those standards.

Public responses came mostly from health-care industry associations, technology vendors and pharmaceutical distributors and manufacturers, the majority of which recommended RFID technology, with many recommending 2-D bar-coding as a backup up technology in the event an RFID tag failed, and urging the FDA to consider using GS1 standards for either technology. Several vendors of nanotechnology products recommended their own solutions for authentication, while several individuals also responded, stating that any pedigree system was going to be a burden for pharmacies and health-care providers.

While most of the responders agreed that non-line-of-sight technology—which thus far is provided only by RFID—was the most effective solution for track and trace as well as for authentication, there were concerns about its cost and

accuracy and whether the RF waves would degrade or affect the quality of the pharmaceutical that is being tracked.

The California State Board of Pharmacy commented, “We are encouraged by the timely request for information and support expeditious action by the FDA in this vital standards-setting endeavor.” Of the states that have independently been pursuing a pedigree system for drugs that enter their borders, California has made the most progress. The California pedigree law was first enacted in 2004, with an initial effective date of January 1, 2007, and then modified and extended in 2006 to Jan. 1, 2009. Recently, the board further extended the effective date for implementation of the pedigree requirements to Jan.1, 2011. The board noted in its statement to the FDA that both the FDA and California prefer—and assume the FDA’s recommended system will utilize—RFID technology.
The FDA should seek guidance from GS1’s EPCglobal division for recommending an RFID standard, the board wrote.

GS1, in its own public comment, indicated that the FDA, whether using 2-D bar-coding or RFID technology, should follow a GS1 standard. “We recommend that the FDA work with the industry and provide them enough room to develop [a system] that is best for them,” says Bob Celeste, GS1’s health-care director. Celeste points out that Florida’s efforts at developing a statewide e-pedigree system resulted in nothing more than a paper-based pedigree system, in part because the initial system was too rigid. “That makes it difficult for industry to comply,” he says.

When it comes to technology other than RFID, the California Board of Pharmacy stated, “We are unfamiliar with any encryption technology or nanotechnology applicable to this task.” That leaves 2-D bar codes and RFID tags, and of the two, the board reports, “RFID is a vastly superior technology for all of the purposes served by an electronic pedigree/track and trace system, and should be the industry standard for data carriers.” The board added that, “2-D bar codes have utility

as a temporary or interim solution, and as a backup technology on packaging in the event of a (rare) RFID tag failure."

According to the board, the only disadvantage that RFID has compared with 2-D bar codes is its higher cost of implementation. "But RFID costs have plummeted recently, and will fall farther. Moreover, the costs of RFID are substantially outweighed by its benefits," wrote the board, noting that RFID tags are less easily counterfeited or duplicated than are other data carriers, including 2-D bar codes.

Addressing a concern as to whether RFID has an effect on the quality of the products' biologics, the board stated, "To date, all of the available data of which the board is aware suggests there is no such effect, and the board has not been made aware of any studies or data demonstrating any such effect."

Pharmaceutical company Merck advised the FDA to consider a single numeric identifier standard with structured codes rather than national drug code (NDC) numbers to protect privacy and to avoid duplication in the field. NDC numbers would identify which kind of product is being transported. "We recommend reliance on a global serialization standard that GS1 Healthcare would determine," the company wrote in its submitted comments.

GS1 currently utilizes a global trade identification number (GTIN) that includes an NDC. While the NDC indicates the kind of product, it is not recognized outside the United States. With the GTIN, however, the NDC can be used in the United States while the GTIN itself is still recognized outside of the United States. In this way, says Celeste, a product could be shipped from one country and the same identifier could be used there as well as in the United States.
When it comes to cost of technology infrastructure, Merck reported its engineering studies found that it costs

approximately $1.3 million to retrofit one existing packaging line for serialization—either 2-D bar-coding or RFID.

The American Society of Health-System Pharmacists (ASHP) commented that RFID could be adopted in situations where bar codes are currently being employed for tracking and tracing, but encryption would be necessary to guarantee security of product information.

“For automatic tracking, encryption should be used in any portion of the supply chain that could be compromised by an outside source,” the ASHP urged. “It would be beneficial to encrypt all prescription drug-related communications.” The ASHP also recommended the FDA mandate using the EPCglobal’s Electronic Product Code (EPC) RFID standard, as did Healthcare Distribution Management Association (HDMA). HDMA recommends that the FDA include provisions for a single non-line-of-sight technology such as RFID, as the primary data carrier. It also recommends that the FDA provide for a single secondary data carrier—the 2-D bar codes—to back up RFID. HDMA argues that non line-of-sight technologies are harder to duplicate and therefore provide greater security. The organization says it is also more efficient for the high-volume, high-throughput operations of the typical healthcare distributor.

Representing retail chain pharmacies and suppliers, the National Association of Chain Drug Stores NACDS was less enthusiastic about RFID. In its comments, the organization stated that prescription drug tracking and tracing technologies, although promising, are yet to be reliable and acceptable: “Many benchmarks must be met before prescription drug tracking and tracing is ready for use across the drug distribution supply chain.”

When it comes to the unique standard numerical identifier, for example, NACDS wrote, adoption of a standard numerical identifier is only the first step toward a tracking and tracing system. “After the standard for the numerical

identifier is announced, many steps must follow. The producers of the data carriers will need time to design, develop, test and manufacture the data carriers."

The group stated that from retail pharmacy's perspective, "non-line-of-sight readability would make the identification and track and trace system more efficient and less costly for ongoing operations." The NACDS cited a study conducted by one of its members that found that 2-D bar codes are time-consuming and inefficient due to the manual scanning process. "However, challenges exist for RFID as well, such as the upfront capital expense and the lack of maturity of the technology." NACDS said that because RFID technology is still under development, existing RFID technology could become outdated quickly. "Mandating existing technology could actually frustrate the goal of a stable uniform system. It would be premature for the drug distribution supply chain industry to lock into existing technology that is still under development, evaluation and testing."
The estimated cost for retail pharmacies to comply with a mandate that included RFID or 2-D bar-code technology would be tens of thousands of dollars per store and in excess of $1.6 billion for all the drug stores in the United States, according to the NACDS. These numbers do not include the costs associated with rolling out the technologies in pharmacy distribution centers and costs to adjust to changing technologies.

The HDMA urged the FDA to publish its intentions specific to standards and allow the industry an opportunity to respond before finalization. It also requested the FDA to continually evaluate the standards as counterfeiters work around any standard, and revise them as needed.

Teva Pharmaceutical Industries recommended either using 2-D bar-coding, which it calls "a widely accepted and cost-effective" technology with the ISO ECC 200 standard, or UHF EPC Gen 2 RFID tags with bar-coding as a backup. "RFID is a

promising technology but the readability and cost are barriers for it immediately becoming the standard." Because the readability is not reliable, the company wrote, a backup technology would still be necessary in the event an RFID tag failed.

And the Generic Pharmaceutical Association (GPhA) noted that RFID as well as encryption and nanotechnologies are "nascent and currently not robust enough to ensure a smooth and orderly flow throughout the drug supply chain." RFID is a promising technology, but the readability and cost are barriers for it becoming the standard, the association stated.

Drug manufacturer Pfizer indicated that the FDA should not mandate one technology. "Leave this to the market and individual organizations to decide based on the unique characteristics of the products involved," Pfizer wrote. "If RFID is used for serialization purposes, a second data carrier also will need to be used for select products."

Drug distributors indicated a preference for RFID technology. McKesson stated that it "supports the use of RFID and product serialization at the point of manufacture. In order for this technology to be implemented, manufacturers must embrace RFID and assume the responsibility for placing electronic tags that uniquely identify their products."

Automatic identification association AIM Global indicated that RFID with bar coding as a secondary system was the best solution.

Other alternative authentication systems were recommended by technology vendors. For example, XStream Systems produces a material identification system as an alternative or added layer of authentication. "Our systems perform nondestructive testing of powders, liquids, and pills, all while still sealed in their finished packaging," the company commented.

Bar-code label and UHF EPC Gen 2 RFID tag manufacturer Avery

Dennison submitted comments favoring the adoption of RFID. The company also plans on responding to some of the public comments, says attorney Ronald Quirk, who represents Avery Dennison. Potential harm to biologics, he says, has not been proven in any testing that he is aware of. “There may need to be more studies done,” he adds. In a letter to the FDA, he wrote that Avery Dennison will also address the concern regarding cost. He points out that the cost of Gen 2 UHF RFID tags was approaching the cost of 2-D bar-code labels as the tag costs continue to drop. They are currently 10 cents a tag or slightly less. “Whatever recommendations the FDA comes out with will increase sales exponentially of whatever technology they endorse,” which will serve to lower per-unit costs even further, Quirk adds.