RFID, Nano-Tools and the Electronic Safety Net: Nanotechnology may revolutionize the use of RFID in the battle against counterfeit drug imports

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By Michael F. Cole

As a recent UPS commercial makes clear, boxes can "talk," and they do so with radio frequency identification (RFID) tags. RFID technology is revolutionizing the business of tracking inventory and, soon, the U.S. Food and Drug Administration (FDA) will use it to combat counterfeit drugs. The challenges of RFID adoption, in turn, might act as an additional impetus to the development of nanotechnology solutions.

RFID is a system to transmit information about an object, such as its identity, by using radio waves. FDA views RFID as the most promising technology to combat the flow of counterfeit drugs to U.S. consumers, and encourages the adoption of RFID by manufacturers and distributors.

FDA refers to RFID as an "electronic safety net" that will allow FDA to identify and halt illicit drug transactions. FDA will hold a public workshop and vendor display on Feb. 8-9, 2006, in suburban Washington, D.C., to identify obstacles and incentives for the widespread adoption RFID throughout the U.S. drug supply chain, and to discuss ways to overcome any impediments. The workshop is the latest in a series of initiatives stretching back more than two years to support the adoption of a so-called "track-and-trace" system for drugs and other regulated products.

To oversimplify, RFID technology, as applied to drug distribution, would involve tagging a product as it left the original drug manufacturer. Then, at each stage in the distribution chain, employees (or FDA inspectors) could quickly scan the product on hand and determine whether or not it is genuine. The illicit product could then be traced back to its source and action taken.

Dr. Randall Lutter, FDA associate commissioner, outlined the thinking behind FDA's position in a recent speech. FDA believes that the overwhelming majority of drugs sold in the United States are genuine. Nevertheless, there has been an increase in counterfeiting activities, and the counterfeiters are becoming more sophisticated. Illicit wholesale diverters and others in the supply chain provide the window into the supply system.

Lutter may have had in mind the action taken by FDA and the U.S. Attorney for the Western District of Missouri in 2005. This involved a series of indictments and the shutting down of an extensive operation for the sale of the cholesterol-reducing drug Lipitor. The indictments alleged that the parties involved had manufactured counterfeit Lipitor in Central America, purchased genuine Lipitor intended for distribution in South America and then illegally imported both products for sale domestically.

Lutter outlined the many steps FDA has taken in the last two years to facilitate the adoption of RFID by working with individual companies, supply chain partnerships, business groups, intergovernmental groups and various international bodies. These efforts have been necessary because FDA has indicated that introducing RFID should be "an essentially voluntary approach."

Although some companies have firmly embraced the concept and are studying or implementing an RFID system, others have been reluctant, because of the cost involved in

tagging. Lutter addressed that concern by saying that the benefits of certainty about the supply system would provide savings that would offset any increase in costs. Sounding a bit like a salesperson for an RFID tag supplier, Lutter stated: “While fighting counterfeit drugs is a key part of FDA’s mission to ensure drug safety, we acknowledge important public concerns about the cost of medications and the implications of high costs for access to drugs. Based on discussions with some drug companies and retailers, we believe that RFID can offer significant savings in the form of better inventory management to manufacturers, wholesalers and retailers alike.”

Lutter told his audience that “other savings would stem from reduction in theft and product loss, improved recalls and reduction in paperwork burdens. While desire for these cost savings is understandably the key motivation for your pursuit of RFID, our interests overlap. Thoughtful adoption of RFID, while helping you financially, will also offer a lower-cost way of ensuring authenticity of drugs, thereby providing key support for our fight against diversion and counterfeiting.”

Cost is a major issue. The issue first became more than theoretical when two “800-pound gorillas” -- Wal-Mart and the Department of Defense (DOD) -- decreed that vendors had to meet RFID tagging requirements in order to do business with them. Many of the items supplied to those entities were not high-profit-margin items, and potential tag costs of $0.30 to $1.00 or more per unit sparked a major debate about whether the adoption of RFID provided a sufficient return on investment, despite the known advantages. The magical number for making RFID attractive soon came to be described as $0.05 per tag. (See RFID Journal, Feb. 16, 2004.)

Nanotechnology to the Rescue?

The question can be asked: Can the application of nanotechnology be used to surmount the cost obstacle and other concerns? Most discussion to date has focused on the adoption of a passive tag RFID operation for drug products. A reader scans the tag on the pallet or box and sends the data to a host, where the tag responds by displaying the data previously read onto the tag.

If RFID is accepted widely, so that tag manufacturers can achieve economy of scale, the price per tag will go down. People in the industry estimate the cost of the microchip to represent one-third of the cost, while the cost of assembly of the components into a tag represents the balance. Microchip prices will come down as the volume increases, but the need to reduce the cost of assembly is seen as the major way to get the cost of RFID down to where users will realize a reasonable ROI.

The needed innovations in assembly might come about through the increased use of nanotechnology to increase the number of tags that can be produced per hour, lower the cost per tag and increase the amount of information that might be stored on each tag.

Among the nanotechnology developments that may have a lasting effect on the universal use of RFID, one of the early leaders appears to be Alien Technology Corp., Morgan Hill, Calif. The company says it “has developed and holds exclusive patent rights to a revolutionary manufacturing assembly technology called Fluidic Self Assembly (FSA). Invented at University of California, Berkeley, by Prof. John S. Smith, FSA enables efficient placement of very large numbers of small components across a surface in a single operation. FSA has numerous potential uses, including the high-volume manufacture of very inexpensive RFID tags.

“The FSA process allows Alien to package tiny integrated circuits for assembly into RFID tags at rates upwards of two million per hour. This contrasts with the approximately 10,000 per hour possible with conventional methods that were developed to handle much larger and more costly integrated circuits.”

Another nanotechnology company, Nanosys Inc., says its technology, too, might be employed to reduce the cost of RFID tags. “Our thin-film electronics technology may allow us to achieve the electronic performance of silicon wafers over large areas on a lightweight, flexible substrate,” reports the company, which is based in Palo Alto, Calif. “This technology is expected to be compatible with traditional thin-film manufacturing equipment, as well as advanced printable electronics technologies.”

Yet another company is exploring ways to replace the antennas made from copper or aluminum that are currently used on tags with inks containing nano-sized particles that allow antennas to be printed on paper, lowering cost and speeding up production. (See Science Daily, June 6, 2005.) To reduce production time, nanotechnology is also being used to see whether crystal pin nanostructures can be put into the attachment glue used to attach the antenna to the chip. Presently, that glue or paste must have time to cure, and that slows production. With the pins, one application of pressure would make the connection.

More Information

In addition to speeding up production and reducing costs, the ability to store more information on a tag is an important consideration being pushed by both DOD and FDA. The challenge is to get beyond the initial 96 bits of information commonly stored on a tag, and nanotechnology companies are exploring ways to do that, as well.

One company, Micromem of Toronto, Ontario, Canada, is reportedly developing magnetic RAM, or MRAM. According to Science Daily, “unlike all other existing computer memories, which are based on storing electrical charge, MRAM stores information using nano-sized magnetic bits, each akin to a compass needle. A computer writes data into MRAM by flipping each bit’s magnetic polarity allowing data to be kept even when electrical power is removed.”

It is impossible to say which of these technological innovations flowing from the use of nanotechnology will be successful. What is clear is that the initiative of the FDA, following on the heels of the action by DOD and leading retailers, is presenting a golden opportunity for the fledgling companies in the nanotechnology business to demonstrate the commercial viability of many ideas presently on drawing boards or being tested in laboratories.

FDA will no doubt get the RFID system put into widespread use. But when that happens may depend in large measure on the success in using nanotechnology to reduce the cost of the tags, speed their production and increase the data available to the employee or inspector scanning the tags and looking for products that should not be there. In other words, “the devious would-be peddlers of diverted or fake medicines” described by FDA’s Lutter should beware: The nanobots are coming.

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