

FDA Issues New 'Counterfeit Drug Task Force' Report

The agency will not mandate for RFID's use within the pharmaceutical industry, but urges the industry 'move quickly to implement this technology.'

By Beth Bacheldor

June 9, 2006—The [U.S. Food and Drug Administration](#) issued today its much-anticipated report on RFID's use in the pharmaceutical industry, calling the technology "the most promising technology for implementing electronic track and trace in the drug supply chain." The agency has, for several years, advocated the use of RFID tagging at the item-, case- and pallet-level to track and trace pharmaceuticals as a means of fighting counterfeit drugs.

Though the report, [FDA Counterfeit Drug Task Force Report: 2006 Update](#), does not mandate RFID's use within the pharmaceutical industry, it recommends that the industry should "move quickly to implement this technology."

The Task Force consists of senior staff from the agency's Office of the Commissioner (Office of Policy and Planning, Office of the Chief Counsel), Office of Regulatory Affairs, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research. For more than two years, the agency's Counterfeit Drug Task Force has been investigating RFID technology and the concept of an electronic pedigree (e-pedigree), a procedure that records where a drug is manufactured and how it is distributed. In early 2004, the FDA had hoped, by 2006 tagging, the pharmaceutical supply chain would be using RFID tags at the individual item level for all drugs likely to be counterfeited, and tag all drugs at the pallet, case and unit levels a year later (see [FDA Endorses RFID Technology](#)).

At a public workshop last February, acting FDA Commissioner Andrew von Eschenbach requested the agency's Counterfeit Drug Task Force to file a new report by May 2006. That purpose of that report, issued today, is to provide recommendations on how the agency should move forward to make the pharmaceutical supply chain more secure (see [FDA to Update Its RFID Vision](#)).

In the report, the task did not determine whether an RFID tag should be encoded with both a drug's National Drug Code (NDC). The NDC is a product identifier, and some parties have expressed concern that if NDCs was encoded onto RFID tags, the practice could jeopardize the privacy of patients and potentially endanger the drug supply chain. Consequently, the FDA has stipulated should any company opt to record the NDC on the RFID tag, it should also encrypt the NDC.

That requirement is likely to sway companies away from encoding tags with the NDCs, according to Paul Chang, IBM's associate partner of business consulting services. Chang has spent some time advising the FDA on the opportunity and capabilities of RFID. That's because adding any encrypted data to an RFID tag will likely increase the cost of the tag and slow down processing speeds.

Instead, companies will store NDCs and related data on back-end systems, and companies will cross-reference the tag's EPC code to that back-end data. "My sense is most companies will just use the license plate approach [of using the EPC code only], so there is no pertinent information on the tag, just a number that will be used as a reference to get information," Chang says. "And that crushes the privacy debate. If you have specific information on the tag itself, there are probably some means for people to read the tag and perhaps figure out what drug you are taking. Without the NDC on the tag, you'd have to hack into multiple databases to figure out what that number means. I'm not sure you'd use the word impossible, but it is very, very difficult to hack into multiple databases and try and figure out what that drug is."

The report also recommends the ending of a temporary "hold" on regulations related to the Prescription Drug Marketing Act of 1987. That act requires drug distributors to document (via a pedigree, though it does not have to be in electronic form) the chain of custody of drug products as they move through the distribution system. The hold, initiated because there were concerns that pedigrees would have a negative impact on small wholesalers, will expire in December and not be extended, according to the FDA.

The task forces also recommended that the FDA issue a draft Compliance Policy Guide for public comment that would focus FDA's pedigree-related enforcement efforts on those drugs most vulnerable to counterfeiting and diversion; that stakeholders continue moving forward in implementing RFID across the drug supply chain and adopt a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step; and the FDA work with manufacturers and other stakeholders in their efforts to develop appropriate messages, symbols, or statements for labeling of drug products and packaging that contains an RFID tag.

Eschenbach has indicated that he endorses the report and all its recommendations.

The task force, however, remained undecided on one major issue: whether an RFID tag should be deactivated before it leaves the pharmacy, or that patients should be given the choice of whether it is turned off. "We recognize that this is an important issue, but do not have sufficient information to make a recommendation at this time," they wrote.

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