

It's Not That Simple

Don't blame the FDA for not imposing mandates to speed up RFID's adoption in the pharmaceutical industry.

This year, government policy makers will likely decide the future of RFID in the pharmaceutical industry. The direction they choose will affect your business, whether you are a vendor or consumer of RFID products and services.

Many are convinced that if the U.S. Food and Drug Administration had acted more like the U.S. Department of Defense—imposing requirements for tagging drugs—the adoption of RFID for pharmaceuticals would be equally swift and decisive. But that is comparing apples to oranges. The DOD buys billions of dollars' worth of supplies—from bullets to MREs. For many defense contractors, the DOD is their primary—if not sole—market. Most will comply with a DOD contract requirement for RFID rather than risk losing their largest customer.

In contrast, the FDA doesn't buy any drugs; it regulates the safety and efficacy of drugs. The drug industry includes an international network of manufacturers, wholesalers, secondary distributors, chain drugstores, pharmacies, hospitals, Internet vendors and doctors' offices. An FDA mandate for RFID tags on drugs can't be done as a contract requirement—it requires a policy solution that accounts for all of the affected stakeholders to avoid lengthy legal and regulatory hurdles. Case in point: When the FDA tried to speed things along by moving forward with e-pedigree regulations last December, small drug wholesalers sued to block the regulations and won a stay.

In addition, other federal agencies—including the Department of Health and Human Services, and the Department of Veterans Affairs—do buy billions of dollars' worth of drugs. If they decide to require RFID tags on the drugs they buy, it could do more to create a de facto "standard" than any regulations coming from the FDA. And do it faster.

Congress, too, will play a role. During a Congressional hearing last summer, lawmakers questioned the FDA about its e-pedigree plans. Members of Congress did not ask about UHF versus HF tags. They wanted to know how it would impact their particular public-policy priorities—from importing drugs from price-controlled Canada to preservatives in childhood vaccines.

Congressional involvement in legislating and overseeing the FDA's e-pedigree direction will inevitably raise other questions. Who within the pharmaceutical supply chain will be required to participate—and who will pay for the technology? Who will enforce the requirements? What legal liabilities do RFID vendors and their customers have if patients are harmed from inaccurate data? How will products shipped internationally, outside U.S. government jurisdiction, be treated?

For there to be any chance of Congress and the regulatory agencies getting it right, RFID vendors and their customers must work together toward a mutually beneficial solution. Adopting RFID in the pharmaceutical industry will take more than a technology solution—it will require a public-policy solution.

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