

# Keeping Bogus Drugs Out of the Medicine Cabinet

A number of factors are conspiring to significantly increase the potential for counterfeit drugs to wind up in our homes.

By Jan-Willem Reynaerts

Aug. 6, 2007—Recently, Colgate-Palmolive was thrust into a crisis it didn't create, forcing the manufacturer to scramble to have toothpaste bearing its iconic Colgate brand pulled from store shelves in New York, New Jersey, Pennsylvania and other states. The problem? Counterfeit tubes of toothpaste—labeled with the Colgate packaging, and containing diethylene glycol, a sweet-tasting chemical commonly found in antifreeze—had entered the U.S. supply chain via China. Fortunately, those affected by the counterfeit product have, to date, faced only relatively minor medical issues.

To its credit, the company, in cooperation with the U.S. Food and Drug Administration (FDA), has worked diligently to educate consumers regarding the potential dangers of the counterfeit product and how to identify it, while also working proactively to make sure the tainted product was pulled from store shelves.

If the dangers of counterfeit toothpaste leave a bad taste in your mouth, stop and consider the troubles counterfeit heart medication—or any other prescription drug, for that matter—could cause. The probability is greater than you might think.

Last year, nearly 4 billion prescriptions were filled in the United States. Understandably, customers expect the medications they purchase to be authentic, especially those coming from reputable pharmacies. However, greater sophistication by counterfeiters, both inside and outside the country, as well as the importation of drugs through Internet pharmacies and the opportunity for stolen and fraudulently obtained pharmaceuticals to enter the supply chain, all significantly increase the potential for counterfeit drugs to wind up in our medicine cabinets. Ultimately, consumers are left with little choice but to trust the programs and systems currently in place to protect them from the potential dangers or counterfeit products. But how effective are these protections?

The U.S. Congress, the FDA, and numerous pharmaceutical distributors and manufactures have attempted to collectively address this issue, with little progress. Twenty years ago, following an alarming increase in counterfeit drug cases in the United States, Congress passed the Prescription Drug Marketing Act, requiring drug distributors to document their products' chain of custody, which Congress called a "pedigree" system. Since then, the FDA has issued a number of regulations in an attempt to comply with the law, and has even made public statements of its support of an electronic pedigree (e-pedigree) system based on radio frequency identification—though it has stopped short of mandating such a solution.

Meanwhile, the threat continues to grow. In 2005, the FDA thwarted a drug counterfeiting and smuggling ring that was trafficking almost \$50 million worth of Lipitor into and out of the United States.

Most recently, through the context of the larger debates over drug importation and Internet drug sales from such countries as Canada and Mexico, Congress has once again stepped in by introducing several bills requiring the implementation of an e-pedigree system. And throughout the political and technological debates among government and industry representatives, what has emerged as a viable, cost-effective solution to securing the pharmaceutical distribution chain is the use of RFID technology in an e-pedigree tracking system.

Utilizing RFID by tagging bottles and authenticating shipments throughout the distribution chain would bring a level of security, efficiency and economic feasibility unmatched by any other technology currently being tested. RFID has already proven effective in distribution and inventory-management systems by large consumer-goods chains, and many pharmaceutical companies have initiated successful pilot programs testing the technology.

RELATED\_ARTICLES More importantly, RFID provides companies the ability to authenticate products throughout the distribution cycle, from the manufacturing facility all the way to the storefront. As a result, opportunities for counterfeiters to bring fake drugs into the supply chain would be nearly eliminated, and pharmacists and hospitals would be more certain of the safety and security of the drugs they dispensed. In addition, manufacturers, wholesalers, retailers and patients could achieve significant savings.

Ultimately, securing our pharmaceutical distribution chain will not be achieved unless Congress, the FDA and the pharmaceutical industry work together to agree on an appropriate solution and timetable for implementing a secure e-pedigree system. With some political foresight and follow-through, policymakers and industry leaders could largely prevent a Colgate incident from ever happening to your prescription drugs.

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