

Two U.S. Bills Might Lead to RFID Mandates

If they pass into law, the proposed legislation could result in RFID-tagging requirements for drugs sold via the Internet and for all tobacco products.

By Beth Bacheldor

March 7, 2007—Two proposed federal bills—though not naming RFID specifically—could become legislative catalysts for the technology's use in government regulation.

In an effort to shutter disreputable Internet pharmacies and help improve drug safety for consumers, U.S. Senator Judd Gregg (R-N.H), a member of the Senate Health, Education, Labor and Pensions Committee, along with Senator Gordon Smith (R-Ore.), introduced a bill mid-February that calls for track-and-trace technologies to be used on drug shipments. The Safe Internet Pharmacy Act of 2007, [S.625](#), seeks to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of Internet pharmacies.

Though it doesn't specifically mention RFID, the bill will likely be influenced by the [U.S. Food and Drug Administration](#), which is urging pharmaceutical companies to use RFID to track drugs within the supply chain in order to fight drug counterfeiting and create electronic pedigrees, or e-pedigrees (see [FDA Issues New 'Counterfeit Drug Task Force' Report](#)). E-pedigrees record where a drug is manufactured and how it is distributed.

Specifically, the bill would require Internet pharmacies "to affix to each shipping container of drugs to be shipped in the United States such markings as the Secretary [of Health and Human Services] determines to be necessary to identify that the shipment is from a licensed Internet pharmacy, which may include anticounterfeiting or track-and-trace technologies."

The Safe Internet Pharmacy Act would also require, among other things, that all Internet pharmacies that dispense prescription drugs in the United States be licensed by the Food and Drug Administration, and requires them to display a tamper-resistant "seal of approval" on their Web sites to help consumers determine if they are licensed by the FDA.

The legislation addresses concerns that Internet shoppers may be buying unsafe or counterfeit pharmaceuticals from unregulated and unscrupulous Internet vendors, according to Doug Farry, managing director and chair of the RFID practice at [McKenna Long & Aldridge](#), a nationwide law firm that focuses on public policy and technology. Farry also oversees McKenna Long's [RFID Law Blog](#).

According to Farry, Congress plans to get involved in the question of whether and how RFID will be used in the pharmaceutical space. "The Gregg legislation does not use the term RFID but requires tagging and tracking of pharmaceuticals as a condition of being licensed to provide Internet sales in the U.S. It is 'placeholder' language in the recognition of the fact that the FDA has plans for e-pedigrees for similar purposes that may or may not ultimately require RFID by regulation," Farry says.

The Safe Internet Pharmacy Act of 2007 has been referred to the Senate Committee on Health, Education,

Labor and Pensions for review. Farry says the bill has only begun to move through the process, but if Congress does dictate an outcome on what the FDA or the industry must do regarding Internet pharmacies, that law will supersede any regulations the FDA has in place.

Farry says the Safe Internet Pharmacy Act of 2007 is expected to be rolled into the reauthorization of the Prescription Drug User Fee Act (PDUFA), a law that requires drug companies to pay a fee that finances the FDA's drug testing and approval infrastructure. Because of that, the act may get through sooner than later. "The FDA's authority [to test and approve drugs] expires on Sept. 30, 2007, unless Congress reauthorizes it, so it is considered must-pass legislation if Congress wants to avoid blame for shutting down the FDA for a year," Farry says.

Meanwhile, Sen. Ted Kennedy (D-Mass.) and Rep. Henry Waxman (D-Calif.) introduced bills on February 15 (S.625 to the Senate, and H.R. 1108 to the House) that would grant the FDA the authority to regulate the manufacture, sale and advertisement of cigarettes and smokeless tobacco. The bills, both entitled The Family Smoking Prevention and Tobacco Control Act, say the government may require codes or devices on tobacco product labels "for the purpose of tracking or tracing the tobacco product through the distribution system."

RELATED_ARTICLES Again, the proposed tobacco bills do not call for the use of RFID, but Farry says they could, "if there was interest in doing so." Of note is the fact that Kennedy's prime cosponsor of the bill is Sen. John Cornyn (R-Texas), who is a cochair of the Senate RFID Caucus, Farry says.

The bills' tagging requirements reflect a desire to prevent tobacco sellers from circumventing any mandated payments toward the global tobacco settlement agreement resulting from the state lawsuits against the industry, he says Farry, who expects the bills to pass by a strong margin this year.

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