

U.S. Senate Bill Proposes Technology to Authenticate Drugs

An amendment passed last week specifying several authentication technologies without mentioning RFID. Some experts say the legislation is confusing.

By Beth Bacheldor

May 18, 2007—The U.S. Senate passed a bill last week that includes an amendment calling for drug authentication technologies to help improve the safety of pharmaceuticals sold on the Internet. However, some confusion exists as to exactly which types of technologies, if passed, the amendment would require.

Authored by Senator Michael Enzi (R-Wyo.), the amendment was added to the Safe Internet Pharmacy Act of 2007, introduced in the spring by U.S. Senator Judd Gregg (R-N.H.), a member of the U.S. Senate Committee on Health, Education, Labor & Pensions (HELP), as well as Senator Gordon Smith (R-Ore.). That act, designed to regulate Internet pharmacies, was a provision rolled into Food and Drug Administration Revitalization Act (S.1082). S.1082 reauthorizes the Prescription Drug User Fee Act (PDUFA), a law requiring drug companies to pay a fee that finances the U.S. Food and Drug Administration's infrastructure for testing and approving drugs (see Two U.S. Bills Might Lead to RFID Mandates). The PDUFA expires on Sept. 30. Congress is expected to reauthorize the act, but the FDA would have no money to continue operating Congress it failed to do so.

Enzi's amendment calls for a specific drug-authentication technology—something the Safe Internet Pharmacy Act of 2007 did not do. Instead, that act calls for 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."

Enzi's amendment, however, demands that drugs sold on the Internet have "overt optically variable counterfeit-resistant technologies that are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices or scanners." The amendment refers to technologies that "are similar to that used by the Bureau of Engraving and Printing to secure United States currency," such as microdots and holograms.

The second part of the amendment provides an alternative, allowing drugs sold on the Internet to be authenticated by means of technologies utilizing a security function comparable to that described above.

Craig Orfield, HELP's communications director, says the amendment is not meant to mandate the use of one particular type of technology. Rather, he explains, it is designed to allow for the use of either a system similar to that used to authenticate U.S. currency, or an electronic system such as RFID.

Some experts, however, say the amendment may be confusing, and could be interpreted to read that pharmaceuticals sold on the Internet must—at a bare minimum—have counterfeit-resistant technologies that

can be detected visually, without the use of interrogators, scanners or other devices.

Some might surmise that even though RFID can be used, they'd still need to support technology that is visible to the naked eye, says Doug Farry, managing director and chair of the RFID practice at [McKenna Long & Aldridge](#), a nationwide law firm focused on public policy and technology. Farry also oversees McKenna Long's [RFID Law Blog](#).

Also of concern to Farry is that the Senate passed the bill reauthorizing the PDUFA with little, if any, discussion regarding Enzi's amendment. Apparently, no input was solicited from leaders within the RFID industry who could have proposed that the technology be mentioned in the amendment. "No one in the industry," he says, "noticed or had any apparent strategy to push solutions that supported RFID."

The FDA has been advocating the use of RFID by pharmaceutical companies 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.

RELATED_ARTICLES Still, Farry says, the amendment's failure to mention RFID doesn't surprise him. The PDUFA is considered must-pass legislation, he says, "so everyone is trying to load up as much as they can in this legislation." In addition, lobbyists who support microdots, holograms and other identifiers difficult to forge have been promoting the use of those technologies for years. "This is not the first time," notes Farry, "that this kind of language [seen in the Enzi amendment] has floated around for different types of applications."

Surprising or not, if similar language appears in the U.S. House of Representative's version of the PDUFA and the Safe Internet Pharmacy Act of 2007, it's likely to have ramifications. For example, drug manufacturers, wholesalers and others that might have adopted RFID may opt to wait until the Secretary of Health and Human Services recommends authentication technologies.

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