

# Congress Weighs Drug Anticounterfeiting Bill

Recently introduced legislation would compel the FDA to require drugmakers to incorporate counterfeit-resistant technologies, such as RFID, into the packaging of prescription drugs.

By Mark Roberti

March 2, 2006—Congressmen Gil Gutknecht (R-Minn.) and Dan Burton (R-In.), joined by seven other members of the U.S. House of Representatives, have introduced legislation aimed at stemming the rising tide of counterfeit and fraudulent prescription drugs presently entering the United States drug supply chain. The Reducing Fraudulent and Imitation Drugs Act of 2006 calls for the incorporation of counterfeit-resistant tools, such as radio frequency identification for tracking and tracing, into the packaging of prescription drugs.

The bill, also known as H.R. 4829, states that the Secretary of Health and Human Services, who oversees a number of U.S. agencies including the U.S. Food and Drug Administration (FDA), "shall require that the packaging of any prescription drug incorporate (1) radio frequency identification (RFID) tagging technology, or similar track and trace technologies that have an equivalent function; (2) tamper-indicating technologies; and (3) blister security packaging when possible."

"Congressman Burton and I have been working on this for several years," Gutknecht says. "The Government Reform Committee had a hearing about four years ago to look at the problem of counterfeit drugs. Many people believe they are coming in from other countries—and some are—but some are originating here in the United States."

Florida has enacted a pedigree law that, starting July 1, will require pharmaceutical companies to document the chain of custody of drugs in the state. California has passed a law with similar requirements that will come into effect on Jan. 1, 2007, while other states are considering various types of pedigree laws, as well. One danger is that pharmaceutical companies will need to comply with 50 different pedigree requirements.

"If we don't get out in front of this issue, you will wind up with a patchwork of rules in every one of the 50 states," says Gutknecht. "This is clearly an issue of interstate, intrastate and international commerce. Personally, I'm disappointed the FDA hasn't acted already. This shouldn't require an act of Congress."

Gutknecht stresses that the drug supply chain in the United States is safe, but claims that because drugs have gotten so expensive, the temptation for criminals to counterfeit them is rising. There are also growing concerns among Gutknecht's constituents, and those of other legislators, that the drugs they buy might be counterfeit.

The next step is for the House Committee on Energy and Commerce and perhaps other House committees to consider the bill, which has bipartisan support. If the committee passes it, H.R. 4829 would go to the floor of the House. The prospects for passage are unclear, and it's not yet known whether any senators plan to introduce the bill in the Senate.

It's also unclear whether the pharmaceutical industry will try to fight the bill. If enacted, H.R. 4829 could raise

costs for the industry by requiring the tagging of all prescription drugs. On the other hand, if the FDA were to set a national standard for creating pedigrees, that would be better for drug companies than having to comply with 50 different laws.

Gutknecht believes the introduction of the bill might put pressure on the FDA to require RFID-tagging of goods to facilitate the creation of electronic pedigrees—secure documents detailing the chain of custody as drugs move through the supply chain.

The FDA published a report in February 2004 encouraging the use of RFID to reduce counterfeiting (see [FDA Endorses RFID Technology](#)), and also held recent hearings on the pharmaceutical industry's progress toward adoption. At the meeting, acting FDA Commissioner Andrew C. von Eschenbach asked the agency's Counterfeit Drug Task Force to file a new report to the FDA by May 2006, containing recommendations on how the FDA should move forward to make the pharmaceutical supply chain more secure (see [FDA to Update Its RFID Vision](#)).

"Congressman Burton and I have said from the very beginning that we want to make sure that the drugs Americans take are safe, effective and affordable," says Gutknecht. "[Enacting this bill] would be a giant step in the right direction. The technology is available today, and it is affordable. The FDA needs to step up and take the lead. That's the bottom line."

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