

Congress Holds Hearing on Ways to Stop Counterfeit Drugs

The Subcommittee on Criminal Justice, Drug Policy and Human Resources heard testimony from representatives of pharmaceutical and RFID firms.

By Beth Bacheldor

July 14, 2006—Congress held a hearing this week focusing on measures designed to secure and prevent counterfeit drugs from entering the pharmaceutical supply chain.

Conducted Tuesday by the Subcommittee on Criminal Justice, Drug Policy and Human Resources, the hearing was attended by representatives of pharmaceutical firms and at least one RFID technology provider. The subcommittee, part of the U.S. House of Representatives' Committee on Government Reform, is responsible for authorizing legislation for the Office of National Drug Control Policy and its programs, as well as general oversight for all U.S. government drug-control efforts. It held the hearing to investigate the threat of counterfeit drugs within the United States and focused on measures to prevent counterfeits from entering the pharmaceutical supply chain, and to improve supply chain security.

The hearing follows the U.S. Food and Drug Administration's updated Counterfeit Drug Task Force Report, issued in June (see FDA Issues New 'Counterfeit Drug Task Force' Report), in which the task force recommended lifting the stay on implementing the "pedigree" rule required in the Prescription Drug Marketing Act. That act requires drug distributors to document the chain of custody of drug products as they move through the distribution system via a pedigree: a document, either paper-based or electronic, that details a drug's genealogy, or history, of who manufactured it and who else handled it as it traversed the supply chain. The FDA agreed to the task force's recommendations, and will fully implement the PDMA regulations, which will take effect Jan. 1, 2007.

In his opening statements at the hearing, subcommittee chairman and U.S. Representative Mark Souder (R-Indiana) told attendees that the FDA's decision "to implement the pedigree requirement is a welcome—if overdue—effort in the national fight against counterfeit medicines in the pharmaceutical supply chain." He went on to say that electronic pedigrees could be accomplished through RFID.

Though the FDA has not mandated the use of RFID as part of a pedigree, the agency is an advocate of the technology. It also is looking to Congress for guidance in the use of RFID. In fact, in the conclusion of its June report, the FDA stated that it recognizes "there are important issues that still need resolution, such as privacy concerns and uniform and universal pedigrees that might benefit from further discussion by stakeholders or Congress."

Douglas Farry, a managing director in the government-affairs practice of law firm McKenna Long & Aldridge, says the hearing's intent may be to help establish that guidance. "There's an awareness of the fact that the FDA had come out with recent change [the decision to implement the PDMA] in its regulations, and so Congress has an oversight responsibility to understand what the regulatory agencies are doing and what the

impacts will be."

After reading transcripts of the subcommittee hearing and talking with congressional staffers who attended it, Farry says several points raised during testimony will warrant further consideration by the pharmaceutical industry, the government and other stakeholders. One has to do with how the use of RFID throughout the pharmaceutical supply chain might be funded, and the other centers on what entities would be liable should counterfeit drugs get through the supply chain despite the use of RFID technology to prevent that from happening.

"These are below-the-radar-screen types of issues, but we've been talking with folks about RFID for some time, both in the government and pharmaceutical markets," says Farry, who is also the lead correspondent for his firm's [RFID Law Blog](#). "One thing we often hear is, 'Great, but who is going to pay for that [RFID]?'"

Indeed, Susan Winckler, vice president of policy and communications for the [American Pharmacists Association](#) (APhA), testified that while APhA supports efforts, including advanced technologies, to combat drug counterfeiting, its support is tempered by the need to minimize the impact on patients and recognizing the reality that pharmacists have limited resources in time and money. "Any anticounterfeit initiatives must include assessments of both the costs and benefits," she told the subcommittee. "As Congress seeks to close gaps in our system, it must assess the impact any proposed solutions might have on pharmacists and our ability to serve patients."

Winckler was one of six speakers who presented testimony during the hearing. Others in the group included the FDA's acting associate commissioner for policy and planning; Kevin Delli-Colli, deputy assistant director of the Financial and Trade Investigations Division, Office of Investigations, U.S. Immigration and Customs Enforcement; Carmen Catizone, executive director of the [National Association of Boards of Pharmacy](#); John Gray, president and CEO of the [Healthcare Distribution Management Association](#) (HDMA); and Rick Raber, project manager of [Northern Apex-RFID](#), a systems integrator.

Several of speakers indicated the need for coordination among various the states' current and forthcoming drug-pedigree laws and the development of RFID standards. Standards continue to be a concern of many stakeholders, including pharmaceutical companies and the FDA. Joseph Pearson, business development manager at [Texas Instruments](#), an RFID tag and chipmaker and one of Northern Apex-RFID's business partners, says the creation of a single item-level standard for the pharmaceutical industry would be a driving factor in RFID's mass adoption in that industry, as would the passage of legislation requiring the use of RFID technology to track the drugs in the supply chain.

"The hearings represent the need for congressional legislation to provide the mandate directive that the FDA is looking for, so they can provide the rules to implement RFID in the industry," says Pearson, who did not attend the hearings, but spoke with several who did.

It is unclear where the subcommittee's hearings will lead, but Farry says Congress has numerous options at its disposal, including acting on the FDA's decision to lift the stay on the PDMA (such as blocking that decision—a move Farry says is unlikely) or creating policy guidelines.

"Whether Congress does that through legislation or oversight and guidance, it has lots of tools at its disposal," he says.