

U.S. Congressmen Seek to Specify a Track-and-Trace Technology for Drugs

At a House Committee on Energy and Commerce meeting, Reps Steve Buyer and Jim Matheson questioned the FDA and sought to gain support for HR 5839, which would require the FDA to stipulate the technology to be used for a nationwide pedigree system.

By Claire Swedberg

May 1, 2008—U.S. House Representatives Steve Buyer (R-In.) and Jim Matheson (D-Utah) joined a hearing of the House Committee on Energy and Commerce today to glean support for a bill that would mandate the FDA to generate a unified track-and-trace pedigree standard for pharmaceuticals as they travel through the supply chain. The sponsors hope that their bill, Safeguarding Pharmaceuticals Act of 2008 (HR 5839), will be included in the Food and Drug Administration Globalization Act—broader legislation the committee is reviewing and preparing to present to the House of Representatives.

HR 5839 reads similarly to the Food and Drug Administration Amendment Act (FDAAA) that passed in 2007 to dictate the creation of a drug identification recommendation that must be completed by the FDA by the end of March 2010. HR 5839 goes farther, however, in that it requires, by the same date, that the FDA issue a track-and-trace recommendation that could spell out the technology to be used for a unified pedigree system. With HR 5839, the FDA would also propose a list of high-risk pharmaceuticals that must be tracked most urgently, and then require the manufacturers of those drugs to comply with the FDA recommendation for a pedigree solution within 18 months after it makes its recommendations in March 2010.

The bill mentions RFID as one technology that could be used in an e-pedigree system. However, the bill is intended to be technology neutral, according to Congressman Matheson's communications director, Alyson Heyrend.

Congressman Matheson, Heyrend says, "is concerned with the hodgepodge of efforts state by state for a pedigree system." The hope with this bill is to mandate the FDA to create one uniform national standard rather than allow each state to develop its own standard. "Obviously, he thinks this bill is the way to go with those key concerns," she says. While the FDAAA requirement also puts the standardization in the hands of the FDA, it does not specifically require the track-and-trace technology to be standardized.

HR 5839 would also allow the FDA to destroy any pharmaceuticals that are proven to be tampered with, counterfeit, misbranded or diverted at some point in the supply chain. Such tampering could be identified, for example, at the port of entry into the United States. At the subcommittee hearing this morning, Ilisa Bernstein, the FDA's senior advisor for regulator policy, told Buyer that currently, in such cases the FDA sends a letter of detention to the receiving party of the questionable pharmaceuticals and gives that party 20 days to respond to the letter. If the FDA does not receive a response, the FDA or U.S. Customs and Border Protection (CBP) in the case of products seized as they enter the country, then either send the drugs back to the sender, or keep them on a shelf for 90 days before destroying them. With the new measure, the FDA or CBP would be allowed to go to the site where the questionable pharmaceuticals are being held and simply destroy the

product immediately. Bernstein told Buyer that "streamlining the destruction authority would certainly be beneficial."

In May 2007, the U.S. Senate passed a bill that included an amendment to the Safe Internet Pharmacy Act of 2007 calling for drug authentication technologies to help improve the safety of pharmaceuticals sold on the Internet (see [U.S. Senate Bill Proposes Technology to Authenticate Drugs](#)). However, the Internet Pharmacy Act of 2007 was not passed by the Committee on Health, Education, Labor, and Pensions and never made it to the Senate floor for consideration.

In April California extended the deadline for an e-pedigree system in its state (see [All Eyes on FDA for Drug Pedigree](#)) from 2009 to 2011 because the pharmaceutical industry indicated it would not be able to meet the 2009 deadline.

At the hearing Thursday morning, Buyer asked about FDA support of a unified pedigree system. Bernstein responded that "a pedigree system provides transparency and accountability through the supply chain. That helps not only ensure [consumers receive] a safe product, but allows regulators to trace back through the supply chain." She said the FDA supports one uniform national standard but does not specify a specific track-and-trace standard or recommend a specific technology.

RELATED_ARTICLES When Matheson asked, "Where is the technology now?"—seeking a response as to whether technology had evolved enough to provide affordable pedigree solutions—Bernstein responded, "There has been tremendous progress on technology and standards," in the past four years.

A spokesperson for Buyer, who asked not to be named, said the congressman was concerned about the selling of pharmaceuticals via Internet, which was one way counterfeit drugs may be entering the country from international markets. By requiring that drug manufacturers follow a standardized track and trace method, that problem could be alleviated, according to the spokesperson.

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