

# GAO Issues Drug Report, Senator Sponsors Bill

A Government Accountability Office report urges FDA reforms; Senator Vitter introduces the Reducing Fraudulent and Imitation Drugs Act.

By Beth Bacheldor

May 10, 2006—The U.S. Federal Drug Administration (FDA) needs to improve the management and oversight of drug safety, according to a recent report issued by the Government Accountability Office (GAO). The report, titled *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process*, scrutinizes the FDA's organizational structure and postmarket drug-safety decision-making processes.

In particular, the GAO pointed to several reorganizations and a high turnover rate that has plagued the agency's Office of Drug Safety, which—together with the Office of New Drugs—oversees the safety of drugs once they've entered the market. The report also cites unclear and ineffective processes, which the GAO says it observed after examining four case studies of drugs with known safety issues: Arava, Baycol, Bextra and Propulsid.

The GAO acknowledged that the FDA faces data constraints, including resource limitations for obtaining data. However, it says, the FDA does have its eye on new technology—in particular, RFID—that could enhance its ability to track and trace drugs as they are manufactured, distributed, sold and prescribed. This month, the agency is expected to release a report outlining recommendations on how it should move forward to make the pharmaceutical supply chain more secure.

The FDA's new report, according to an agency spokeswoman, will include recommendations for faster adoption of RFID and other electronic track-and-trace methods. In response to the GAO's report, she says, the FDA is currently working to change the methods the agency's medical and scientific staff uses to manage safety issues associated with prescription medicine. "Many significant reforms have already taken shape," she explains, "and are leading to improvements in how we and the public health community identify, assess, manage and communicate emerging drug safety information."

## **Senator Vitter Introduces the Reducing Fraudulent and Imitation Drugs Act**

Legislation aimed at cracking down on prescription drug counterfeiting got a shot in the arm late last month when U.S. Senator David Vitter (R-La.) introduced the Reducing Fraudulent and Imitation Drugs Act (S.2668).

The act, if passed, would require manufacturers to use counterfeit-resistant technologies in the packaging of prescription drugs. Examples include sealing drugs individually in plastic rather than the current practice of packaging them loose in bottles, as well as using microscopic tracking devices, such as RFID tags, on packages and cases of pharmaceuticals. The goal is to provide measures that monitor and record where drugs originate and travel throughout the supply chain, and how they are handled.

Congressman Gil Gutknecht (R-Minn.), along with Dan Burton (R-In.) and seven other members of the U.S.

House of Representatives, introduced the same bill, also known as H.R. 4829, to the House on March 1 (see Congress Weighs Drug Anticounterfeiting Bill). On Mar. 17, H.R. 4829 was referred to the health subcommittee of the House's Energy and Commerce Committee, where the bill is still being considered.

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