



Highlights of [GAO-07-599T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In 2004, several high-profile drug safety cases raised concerns about the Food and Drug Administration's (FDA) ability to manage postmarket drug safety issues. In some cases there were disagreements within FDA about how to address these issues.

GAO was asked to testify on the effectiveness of FDA's postmarket decision-making process.

This testimony is based on *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process*, [GAO-06-402](#) (March 31, 2006). The report focused on the complex interaction between two offices within FDA that are involved in postmarket drug safety activities: the Office of New Drugs (OND), and the Office of Drug Safety (ODS). OND's primary responsibility is to review new drug applications, but it is also involved in monitoring the safety of marketed drugs. ODS is focused primarily on postmarket drug safety issues. ODS is now called the Office of Surveillance and Epidemiology.

For its report, GAO reviewed FDA policies, interviewed FDA staff, and conducted case studies of four drugs with safety issues: Arava, Baycol, Bextra, and Propulsid. To gather information on FDA's initiatives since March 2006 to improve its decision-making process for this testimony, GAO interviewed FDA officials and reviewed FDA documents in February and March 2007.

www.gao.gov/cgi-bin/getrpt?GAO-07-599T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse, (202) 512-7119, crossem@gao.gov.

DRUG SAFETY

FDA Needs to Further Address Shortcomings in Its Postmarket Decision-making Process

What GAO Found

In its March 2006 report, GAO found that FDA lacked clear and effective processes for making decisions about, and providing management oversight of, postmarket drug safety issues. There was a lack of clarity about how decisions were made and about organizational roles, insufficient oversight by management, and data constraints. GAO observed that there was a lack of criteria for determining what safety actions to take and when to take them. Certain parts of ODS's role in the process were unclear, including ODS's participation in the meetings of scientific advisory committees organized by OND to discuss safety issues for specific drugs. In the case of Arava, for example, ODS staff were not allowed to present their analysis of postmarket safety at an advisory committee meeting held to review Arava's safety risks and benefits. Insufficient communication between ODS and OND hindered the decision-making process. ODS management did not systematically track information about ongoing postmarket safety issues, including the recommendations that ODS staff made for safety actions. GAO also found that FDA faced data constraints that contributed to the difficulty in making postmarket safety decisions. GAO found that there were weaknesses in the different types of data available to FDA, and FDA's access to data was constrained by both its authority to require certain studies and its limited resources.

During the course of GAO's work for its March 2006 report, FDA began a variety of initiatives to improve its postmarket drug safety decision-making process, including the establishment of the Drug Safety Oversight Board. FDA also commissioned the Institute of Medicine to examine the drug safety system, including FDA's oversight of postmarket drug safety. GAO recommended in its March 2006 report that FDA take four steps to improve its decision-making process for postmarket safety. GAO recommended that FDA revise and implement its draft policy on the decision-making process for major postmarket safety actions, improve its process to resolve disagreements over safety decisions, clarify ODS's role in scientific advisory committees, and systematically track postmarket drug safety issues. FDA has initiatives underway and under consideration that, if implemented, could address three of GAO's four recommendations. Because none of these initiatives was fully implemented as of March 2007, it was too early to evaluate their effectiveness. In the 2006 report GAO also suggested that Congress consider expanding FDA's authority to require drug sponsors to conduct postmarket studies, as needed, to collect additional data on drug safety concerns.