



Highlights of [GAO-06-402](#), a report to the Chairman, Committee on Finance, United States Senate and the Chairman, 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 have been disagreements within FDA about how to address safety issues. In this report GAO (1) describes FDA's organizational structure and process for postmarket drug safety decision making, (2) assesses the effectiveness of FDA's postmarket drug safety decision-making process, and (3) assesses the steps FDA is taking to improve postmarket drug safety decision making. GAO conducted an organizational review and case studies of four drugs with safety issues: Arava, Baycol, Bextra, and Propulsid.

## What GAO Recommends

To improve the decision-making process for postmarket drug safety, GAO suggests that the Congress consider expanding FDA's authority to require drug sponsors to conduct postmarket studies when needed. GAO also recommends that FDA systematically track postmarket drug safety issues, revise and implement its draft policy on major postmarket safety decisions, improve the dispute resolution process, and clarify ODS's role in scientific advisory committees. In its comments on a draft of this report, FDA stated that GAO's conclusions were reasonable. FDA did not comment on GAO's recommendations.

[www.gao.gov/cgi-bin/getrpt?GAO-06-402](http://www.gao.gov/cgi-bin/getrpt?GAO-06-402).

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](mailto:crossem@gao.gov).

## DRUG SAFETY

# Improvement Needed in FDA's Postmarket Decision-making and Oversight Process

## What GAO Found

Two organizationally distinct FDA offices, the Office of New Drugs (OND) and the Office of Drug Safety (ODS), are involved in postmarket drug safety activities. OND, which holds responsibility for approving drugs, is involved in safety activities throughout the life cycle of a drug, and it has the decision-making responsibility to take regulatory actions concerning the postmarket safety of drugs. OND works closely with ODS to help it make postmarket decisions. ODS, with a primary focus on postmarket safety, serves primarily as a consultant to OND and does not have independent decision-making responsibility. ODS has been reorganized several times over the years. There has been high turnover of ODS directors in the past 10 years, with eight different directors of the office and its predecessors. In the four drug case studies GAO examined, GAO observed that the postmarket safety decision-making process was complex and iterative.

FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues. The process has been limited by a lack of clarity about how decisions are made and about organizational roles, insufficient oversight by management, and data constraints. GAO observed that there is 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 are unclear, including ODS's participation in FDA's scientific advisory committee meetings organized by OND. Insufficient communication between ODS and OND has been an ongoing concern and has hindered the decision-making process. ODS does not track information about ongoing postmarket safety issues, including the recommendations that ODS staff make for safety actions. FDA faces data constraints in making postmarket safety decisions. There are weaknesses in the different types of data available to FDA, and FDA lacks authority to require certain studies and has resource limitations for obtaining data.

Some of FDA's initiatives, such as the establishment of a Drug Safety Oversight Board, a draft policy on major postmarket decision making, and the identification of new data sources, may improve the postmarket safety decision-making process, but will not address all gaps. FDA's newly created Drug Safety Oversight Board may help provide oversight of important, high-level safety decisions, but it does not address the lack of systematic tracking of ongoing safety issues. Other initiatives, such as FDA's draft policy on major postmarket decisions and regular meetings between OND divisions and ODS, may help improve the clarity and effectiveness of the process, but they are not fully implemented. FDA has not clarified ODS's role in certain scientific advisory committee meetings. FDA's dispute resolution processes for disagreements about postmarket safety decisions have not been used. FDA is taking steps to identify additional data sources, but data constraints remain.