



Highlights of [GAO-10-279](#), a report to congressional requesters

Why GAO Did This Study

GAO was asked to review the Food and Drug Administration's (FDA) strategic planning and management. Leading practices in this area include developing strategies to address management challenges and results-oriented performance measures, aligning activities and resources to strategic goals, and enhancing the use of performance information. In this report, GAO examined the extent to which (1) FDA's Strategic Action Plan contains strategies to address its management challenges, and the progress FDA has reported in addressing those challenges; (2) FDA's annual performance measures are results-oriented; (3) FDA has aligned its activities and resources to support its strategic goals; and (4) FDA managers report using performance information in decision making and applying key practices to encourage that use. GAO surveyed FDA managers; analyzed reports on FDA to identify its management challenges; reviewed FDA and other documents, prior GAO work, and surveys of federal managers; and interviewed FDA officials.

What GAO Recommends

GAO recommends that the Commissioner of FDA take several actions to improve FDA's strategic planning and management, such as developing a strategic human capital plan and working to make the agency's performance measures more results-oriented. FDA agreed with the recommendations.

[View GAO-10-279](#) or [key components](#).

To view the e-supplement online, click on [GAO-10-280SP](#).

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FOOD AND DRUG ADMINISTRATION

Opportunities Exist to Better Address Management Challenges

What GAO Found

Overall, while FDA is aware of its challenges and has taken steps to address them, the agency does not fully use practices for effective strategic planning and management. GAO identified five major management challenges that could affect FDA's ability to carry out its mission, and while FDA's 2007 Strategic Action Plan contains strategies to address these challenges, progress has been uneven. Through reviewing reports from GAO, the Institute of Medicine, the Department of Health and Human Services, and the FDA Science Board, GAO determined that FDA's management challenges include recruiting, retaining, and developing its workforce; modernizing its information systems; coordinating internally and externally; communicating with the public; and keeping up with scientific advances. GAO's 2009 survey asked FDA managers whether they thought the agency had made progress in addressing its management challenges. A minority of FDA managers responding to the survey reported that the agency was making great progress on meeting most of these challenges—the exception was for public communication. For example, less than one-half of FDA managers reported great progress in addressing workforce issues. GAO also found that FDA lacks an agencywide strategic human capital plan, which reduces the agency's ability to strategically strengthen its human capital.

FDA's 48 annual performance measures for fiscal year 2010 are not as useful for decision makers as they could be because they are only partially results-oriented. The measures adhere to some of the key characteristics GAO identified in prior work that can help provide decision makers with useful information on an agency's results—for example, they are linked to agency goals. However, FDA's measures do not adhere to other key characteristics because they do not focus on outcomes, address important dimensions of agency performance, identify projected levels of performance for multiyear goals, or fully address identified management challenges.

While FDA has taken steps to align its activities and resources to strategic goals, these efforts in its centers and offices are not clear, making it difficult to connect the agency's use of resources to the achievement of its goals. FDA has aligned its three main types of activities—pre-market review, production oversight, and post-market surveillance—and uses employee performance plans to link individuals' activities to its strategic goals. However, only four of eight centers and offices GAO reviewed clearly documented alignment of their activities to FDA's goals, and only two clearly linked their resources to goals, in part because several centers and offices do not track workload by goals.

In GAO's survey, about one-third to one-half of FDA managers reported using performance information to a great extent in making management decisions—for example, to set program priorities. While training can develop agency capacity to use performance information, less than one-half of FDA managers reported receiving training that could improve and expand the use of performance information.