

February 2010

FOOD AND DRUG ADMINISTRATION

Opportunities Exist to Better Address Management Challenges



GAO

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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.

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Abbreviations

CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFSAN	Center for Food Safety and Applied Nutrition
CVM	Center for Veterinary Medicine
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FSWG	Food Safety Working Group
GPRA	Government Performance and Results Act of 1993
HHS	Department of Health and Human Services
IOM	Institute of Medicine
IT	information technology
NCTR	National Center for Toxicological Research
OC	Office of the Commissioner
OMB	Office of Management and Budget
OPM	Office of Personnel Management
ORA	Office of Regulatory Affairs
USDA	U.S. Department of Agriculture

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United States Government Accountability Office
Washington, DC 20548

February 19, 2010

The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Greg Walden
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Over the past several years, we and others have raised concerns about the ability of the Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services (HHS)—to meet the regulatory responsibilities associated with its mission. That mission is to ensure the safety and efficacy of medical products, such as drugs and medical devices, sold in the United States; ensure the safety of roughly 80 percent of the nation’s food supply; and, most recently, regulate tobacco products sold in the United States.¹ Since January 2009, we have identified FDA’s oversight of medical products as an area of high risk, based in part on FDA’s failure to conduct adequate and sufficient inspections of foreign manufacturers of drug and medical devices sold in the United States.² Similarly, in 2007, we identified the federal oversight of food safety as an area of high risk and called for a governmentwide reexamination of the food safety system.³ In 2008, we reported that FDA’s oversight of domestic and imported fresh produce was limited, and we made several recommendations to improve this oversight.⁴ Other entities, such as the

¹Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, div. A, 123 Stat. 1776 (2009). The act, among other things, provides FDA with the authority to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act.

²GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009).

³GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

⁴GAO, *Food Safety: Improvements Needed in FDA Oversight of Fresh Produce*, [GAO-08-1047](#) (Washington, D.C.: Sept. 26, 2008).

Institute of Medicine (IOM) and the FDA Science Board,⁵ have also raised serious concerns about FDA's ability to meet its regulatory responsibilities. For example, in November 2007, the Science Board reported that FDA's mission was at risk due to various management challenges the agency faced, such as poor information technology (IT) infrastructure. The Science Board recommended, among other things, an infusion of resources. Subsequently, Congress increased appropriations to the agency for fiscal years 2008, 2009, and 2010.

Strategic planning and management can help agencies effectively manage resources and fulfill their mission, and, since the mid-1990s, we have reported on leading practices for effective strategic planning and management.⁶ These practices include establishing long-term goals that support the agency's mission, identifying and developing strategies to address key management challenges, and aligning resources and activities to agency goals. These practices also include developing results-oriented performance measures, among other things, to gauge an agency's progress toward achieving its mission or its program-related goals. Applying these measures, managers can collect and track data about management issues, referred to as performance information. They then can use the resulting performance information to guide decision making and improve results.

HHS has a strategic plan that includes goals related to FDA. In addition, FDA developed its own Strategic Action Plan in Fall 2007 to guide its work and help it to fulfill its mission.⁷ In light of the many concerns about FDA's

⁵The FDA Science Board provides advice to the Commissioner on, among other things, specific complex and technical issues as well as emerging issues within the scientific community, in industry, and in academia. See FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Rockville, Md.: November 2007).

⁶GAO, *Managing for Results: Enhancing Agency Use of Performance Information for Management Decision Making*, [GAO-05-927](#) (Washington, D.C.: Sept. 9, 2005); *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decisionmakers*, [GAO/GGD/AIMD-99-69](#) (Washington, D.C.: Feb. 26, 1999); *Agencies' Annual Performance Plans Under the Results Act: An Assessment Guide to Facilitate Congressional Decisionmaking*, [GAO/GGD/AIMD-10.1.18](#) (Washington, D.C.: February 1998); *Managing for Results: Critical Issues for Improving Federal Agencies' Strategic Plans*, [GAO/GGD-97-180](#) (Washington, D.C.: Sept. 16, 1997); and *Executive Guide: Effectively Implementing the Government Performance and Results Act*, [GAO/GGD-96-118](#) (Washington, D.C.: June 1996).

⁷Department of Health and Human Services, U.S. Food and Drug Administration, *FDA Strategic Action Plan: Charting Our Course for the Future* (Rockville, Md.: Fall 2007).

ability to meet its mission, you asked us to review the effectiveness of the agency's strategic planning and management efforts. In this report, we examine 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.

To conduct our review, we examined laws, regulations, guidance, and leading practices related to FDA and strategic planning. We also reviewed FDA documents, surveyed agency managers, and interviewed FDA and HHS officials. In addition, to address our first and fourth objectives, we conducted a Web-based survey of FDA managers from June through August, 2009. We selected a random, stratified sample of over 400 managers from a population of over 1,200. Over 300 respondents, or about 70 percent of our sample, completed the questionnaire. The survey results can be generalized to the entire population of FDA managers. To produce such results, we based our estimates on all respondents who completed our survey, including those not answering a particular question or those providing the following answer: "no basis to judge/not applicable." We used this same method in our previous governmentwide surveys on performance and management issues. All percentage estimates in this report have a margin of error of plus or minus 10 percentage points or less. Our survey asked FDA managers to provide one of the following five responses to our questions: "no extent," "small extent," "moderate extent," "great extent," and to a "very great extent." In reporting FDA managers' responses, we refer to responses in the categories of "great" or "very great" extent as "great." We are also issuing an electronic supplement to this report that shows a more complete tabulation of our survey results.⁸

To identify FDA's management challenges, we reviewed relevant GAO, IOM, HHS, and FDA Science Board evaluations of FDA since January 2007. To determine whether FDA's 2007 Strategic Action Plan contains strategies to address these challenges, we compared the challenges we identified with our analysis of FDA's Strategic Action Plan and verified this

⁸GAO, *Food and Drug Administration: 2009 FDA Managers Survey on Performance and Management Issues, an E-supplement to GAO-10-279, GAO-10-280SP* (Washington, D.C.: February 2010).

analysis with FDA officials. To examine the progress that FDA has reported toward meeting identified challenges, we reviewed prior GAO and FDA Science Board assessments of FDA as well as documentation that FDA provided to us in which it reported its efforts to address identified management challenges since developing its Strategic Action Plan. We also examined FDA managers' responses to questions in our 2009 survey related to these challenges. To analyze responses to our open-ended questions, two GAO analysts independently reviewed and categorized each response, then reconciled any differences in their independent categorizations. We reported on examples that were illustrative of the responses in any given category.

To determine the extent to which FDA's annual performance measures are results-oriented, we identified several selected characteristics of results-oriented performance measures from prior GAO work.⁹ We compared these characteristics with the 48 performance measures included in the President's fiscal year 2010 budget request for FDA. These performance measures are linked to and organized by FDA's main centers and offices. To determine the extent to which FDA has aligned its activities and resources to its strategic goals, we reviewed leading practices on effective strategic alignment from prior GAO work and Office of Management and Budget (OMB) guidance.¹⁰ We determined the extent to which FDA was consistent with these leading practices by comparing FDA's strategic goals from its 2007 Strategic Action Plan with information on the agency's activities and resources. This information included the fiscal years 2009 and 2010 budget requests, strategic planning documents from FDA's main centers and offices, background documentation on the agency's employee time reporting systems, and examples of individual employees' performance plans. To review FDA managers' use of performance information in decision making, we analyzed responses to seven questions in our 2009 survey measuring managers' reported use of performance information to make different management decisions. To review FDA managers' reported application of practices to encourage the use of performance information, we analyzed responses to four other questions in our 2009 survey that measured managers' reported use of practices to encourage the use of performance information. We compared our survey

⁹GAO/GGD/AIMD-10.1.18 and GAO/GGD/AIMD-99-69.

¹⁰GAO, *Results-Oriented Government: GPRA Has Established a Solid Foundation for Achieving Greater Results*, GAO-04-38 (Washington, D.C.: Mar. 10, 2004); GAO/GGD-96-118; and Office of Management and Budget, Executive Office of the President, OMB Cir. No. A-11, Preparation, Submission, and Execution of the Budget, Sec. 220, p. 1 (2009).

results with the results of an earlier 2007 survey we conducted of federal managers across the federal government.¹¹ (See app. I for more details on our scope and methodology.)

We conducted our work from December 2008 to February 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

In this section, we discuss FDA's responsibilities and organizational structure, as well as leading practices for effective strategic planning and management under the Government Performance and Results Act of 1993 (GPRA) that relate to our reporting objectives.¹²

FDA Responsibilities and Organizational Structure

Under the Federal Food, Drug, and Cosmetic Act, FDA's public health responsibilities are, among other things, to ensure the safety and effectiveness of medical products—drugs, biologics, and medical devices—marketed in the United States; ensure the safety of nearly all food products other than meat and poultry; and, recently, regulate tobacco products.¹³ FDA carries out these responsibilities through six regulatory product centers; its Office of Regulatory Affairs (ORA), which performs fieldwork, such as inspections and enforcement activities, on behalf of all the product centers; and its research arm, the National Center for Toxicological Research (NCTR).¹⁴ Each center and office has distinct

¹¹The results of our 2007 survey are available in the following GAO reports: *Government Performance: Lessons Learned for the Next Administration on Using Performance Information to Improve Results*, [GAO-08-1026T](#) (Washington, D.C.: July 24, 2008); and *Government Performance: 2007 Federal Managers Survey on Performance and Management Issues, an E-supplement to GAO-08-1026T*, [GAO-08-1036SP](#) (Washington, D.C.: July 24, 2008).

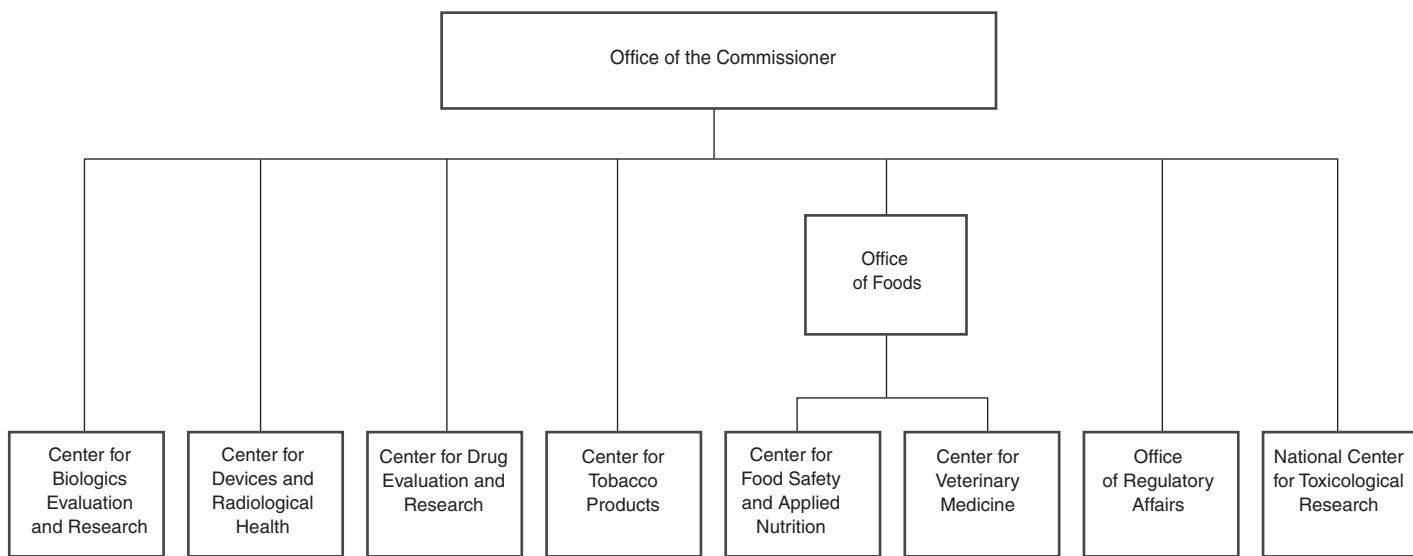
¹²Pub. L. No. 103-62, 107 Stat. 285.

¹³21 U.S.C. §§ 301 et seq.

¹⁴Because the Office of Foods was not established until August 7, 2009, and the Center for Tobacco Products was not established until August 19, 2009, we did not include them in our review.

responsibilities. For example, the Center for Devices and Radiological Health (CDRH) is responsible for ensuring that medical devices are safe and effective and establishes performance standards for radiation-emitting electronic products. Figure 1 shows FDA's main organizational structure, as of August 2009.

Figure 1: FDA's Main Organizational Structure, as of August 2009



Source: FDA.

Selected Leading Practices for Effective Strategic Planning and Management under GPRA

GPRA requires executive agencies to complete strategic plans that define their missions, establish results-oriented goals, and identify the strategies that will be needed to achieve those goals. While the HHS strategic plan fulfills this requirement for its operating divisions, including FDA, FDA has voluntarily developed its own Strategic Action Plan, which it ties to the HHS strategic plan. Under GPRA, executive agencies are also required to prepare annual performance plans that articulate performance measures for the upcoming fiscal year and to report annually on their progress in program performance reports. These reports are intended to provide important information to agency managers, policymakers, and the public on what each agency accomplished with the resources it was given.

In our prior work, we have identified a variety of leading practices for successful strategic planning associated with GPRA that relate to our reporting objectives. As we have noted, these practices can help an agency

achieve its strategic goals and its mission. Some of these practices include the following:

- *Developing strategies to address key management challenges:* We have reported that this practice can improve the quality of strategic plans and provide a pathway to meeting an agency’s long-term strategic goals.¹⁵
- *Creating results-oriented performance measures:* Such measures can be helpful in guiding decisions and assessing performance. We identified practices from our previous work that can help agencies establish performance measures with results-oriented characteristics.¹⁶ Specifically, results-oriented performance measures
 - link to agency and departmental strategic goals,
 - include explanatory information on the measures,
 - show baseline and trend data for past performance,
 - use intermediate measures to show progress or contribution to intended results,
 - focus on expected results by including outcome measures whenever possible,
 - address important dimensions of program performance,
 - identify projected target levels of performance for multiyear goals, and
 - address mission-critical management challenges.
- *Aligning activities and resources to support mission-related goals:*¹⁷ This practice can provide Congress and agency decision makers with a better understanding of how the allocation of resources affects mission achievement.

¹⁵ [GAO/GGD-97-180](#).

¹⁶ [GAO/GGD/AIMD-99-69](#) and [GAO/GGD/AIMD-10.1.18](#).

¹⁷ [GAO/GGD-96-118](#).

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- *Enhancing the use of performance information:* In our prior work, we have observed that agencies can take steps to encourage the use of performance information by employing specific management approaches or tools, such as demonstrating management commitment or developing agency capacity to effectively use performance information.¹⁸ These tools can lead to the improved use of performance information, which can support planning and decision-making functions, which can lead to improved results.

FDA's Strategic Action Plan Contains Strategies to Address Identified Management Challenges, but the Progress FDA Reported Has Been Uneven

Through a review of GAO, HHS, IOM, and FDA Science Board reports on FDA, we identified five major management challenges that could affect FDA's ability to carry out its mission. FDA's 2007 Strategic Action Plan contains strategies to address each of these five challenges. While FDA has reported efforts to address these five challenges, we found that this progress has been uneven.

FDA's Strategic Action Plan Includes Strategies to Address Each of Its Five Identified Management Challenges

We reviewed evaluations of FDA from GAO, HHS, IOM, and the FDA Science Board, and identified five major management challenges that could affect FDA's ability to carry out its mission. These management challenges are (1) recruiting, retaining, and developing a workforce with the knowledge, skills, and abilities necessary to carry out its mission; (2) modernizing information systems, including increasing access to outside data; (3) coordinating internally—among its centers and offices—and externally with other parts of the federal government and outside experts; (4) keeping pace with scientific advances necessary to regulate a diverse and expanding product base; and (5) communicating timely and appropriate product safety information with the public.

FDA's 2007 Strategic Action Plan contains strategies—that is, objectives and specific planned actions under the agency's main goals—to address

¹⁸ [GAO-05-927](#).

each of the five management challenges we identified. Specifically, FDA's Strategic Action Plan includes at least one strategy for each of the five management challenges. For example, in its Strategic Action Plan, FDA lists four objectives related to its management challenge on modernizing information, and, for each of these four objectives, the plan identifies specific actions such as modernizing its IT platform. See table 1 for additional examples.

Table 1: Identified Management Challenges and Examples of Related Strategies in FDA's 2007 Strategic Action Plan

Management challenge	Examples of related strategies in FDA's 2007 Strategic Action Plan	
	Objectives	Specific planned actions
Recruiting, retaining, and developing a workforce	Strengthen the scientific foundation of FDA's regulatory mission	Establish a 2-year FDA fellowship program
Modernizing information systems	Strengthen FDA's base of operations Improve information systems for problem detection and public communication about product safety Improve the medical product review process to increase the predictability and transparency of decisions using the best available science Detect safety problems earlier and better target interventions to prevent harm to consumers	Modernize FDA's IT platform Expand agency officials' real-time access to information related to crises and emergencies Pre-market information tracking warehouse Develop risk-based modeling to identify inspection priorities
Coordinating internally and externally	Enhance partnerships and communications Cultivate a culture that promotes transparency, effective teamwork, and mutual respect and ensures integrity and accountability in regulatory decision making	Establish the White Oak campus as the new venue for scientific and cultural synergy Develop FDA teamwork best practices
Keeping pace with scientific advances	Strengthen the science that supports product safety Increase the number of safe and effective new medical products available to patients Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution	Develop novel technologies for rapid pathogen detection Develop new trial designs for a new era Develop novel technologies for quality evaluations of complex biological products
Communicating product safety information to the public	Enhance partnerships and communications Provide patients and consumers with better access to clear and timely risk-benefit information for medical products Provide consumers with clear and timely information to protect them from foodborne illness and promote better nutrition	Establish an FDA risk communication advisory committee Publish an electronic newsletter on post-market drug safety findings Promote healthy choices by enhancing consumer nutrition information

Source: GAO analysis of FDA's 2007 Strategic Action Plan.

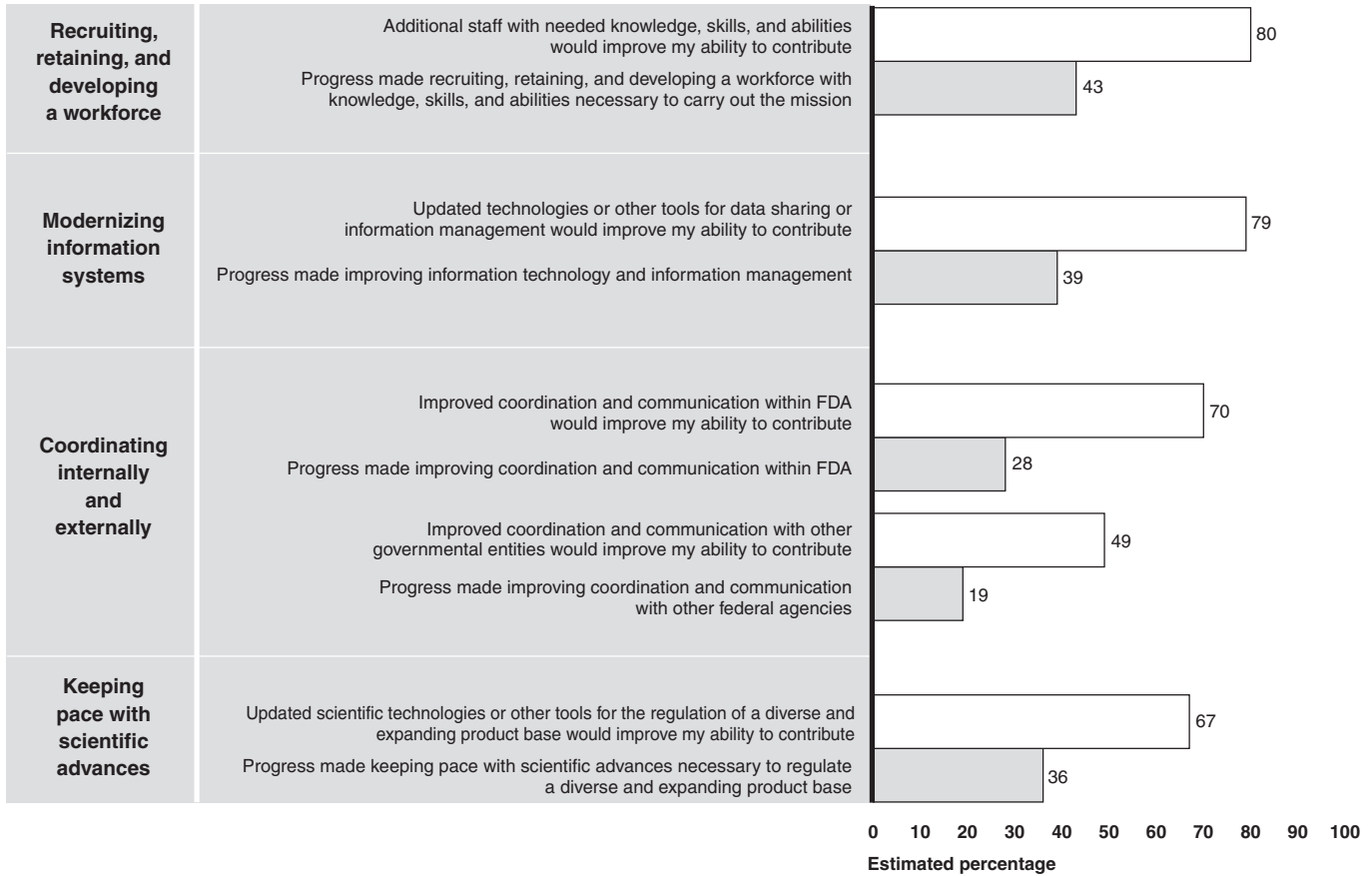
Note: This table provides examples of strategies from FDA's 2007 Strategic Action Plan related to GAO's identified management challenges. A particular strategy can relate to multiple management challenges. The table is intended to be illustrative, rather than a complete list of all applicable strategies for each identified management challenge.

FDA Has Reported Efforts to Address Management Challenges, but the Progress FDA Reported Has Been Uneven

FDA has reported efforts to address each of its five identified management challenges, but the progress FDA reported has been uneven. For example, to meet the challenge of recruiting, retaining, and developing a workforce, FDA has reported meeting internal hiring targets in fiscal years 2008 and 2009. However, because the agency still lacks both a strategic human capital plan and an updated workforce plan, its ability to strengthen its human capital is reduced. Similarly, to address the challenge of modernizing its information systems, FDA has launched new modernization projects and designed policies for investment and project management, but the agency does not have a comprehensive IT strategic plan, among other things, which limits FDA's assurance that it will be able to modernize effectively. To improve its communication with the public, FDA has reported a variety of efforts, and a majority of FDA managers indicated in our survey that the agency was making great progress in this area.

Figure 2 provides a summary of FDA managers' survey responses related to four of GAO's identified management challenges.

Figure 2: FDA Managers' Survey Responses on Areas That Would Improve Their Ability to Contribute to Meeting FDA's Goals and Responsibilities, Compared with FDA Managers' Reporting of Progress Made in Those Areas, by Related Management Challenge



Source: GAO.

Note: Percentages represent survey responses of a “great extent” and “very great extent.” In our survey, we did not ask managers about the extent to which improved communication with the public would improve their ability to contribute to meeting FDA’s goals and responsibilities, so this figure does not make that comparison. In the results, a higher percentage of managers indicated “no basis to judge/not applicable” for the questions asking about “Progress made improving coordination and communication with other federal agencies,” and “Progress made keeping pace with scientific advances necessary to regulate a diverse and expanding product base.” See the full results in our accompanying e-supplement for more information. All percentage estimates in this figure have a margin of error of plus or minus 10 percentage points or less.

Recruiting, Retaining, and Developing a Workforce

FDA has reported various efforts to recruit, retain, and develop a workforce, such as implementing a hiring surge, creating a fellowship program, and drafting an agency succession plan. As it relates to hiring, after receiving an increase in appropriations in fiscal year 2008, FDA

embarked on a hiring surge to fill critical positions, such as medical officers, pharmacists, and consumer safety officers. FDA officials reported that the agency has hired more than 2,500 employees in fiscal years 2008 and 2009. Officials also reported that the agency has exceeded its overall fiscal year 2009 hiring targets, and that most of its centers and offices met or exceeded their individual hiring targets in fiscal year 2009. One manager noted in our survey that increased funding in fiscal years 2008 and 2009 allowed FDA to fill positions that had been vacant for more than 3 years. In addition, FDA has reported efforts to improve training and professional development. For example, in 2008, FDA created a fellowship program to attract scientists to work with mentors in different areas of regulatory science. Additionally, within the centers and offices, various efforts are under way. For example, CDRH and the Center for Veterinary Medicine (CVM) reported that they have initiated a variety of new training programs. The Center for Food Safety and Applied Nutrition (CFSAN) has developed a scientific seminar program, and the Center for Drug Evaluation and Research (CDER), among other things, is developing courses on management and communication. Lastly, in September 2009, FDA completed a succession plan identifying anticipated leadership gaps and workforce needs over the next several years.

While FDA has reported efforts to address the challenge of recruiting, retaining, and developing a workforce, in our 2009 survey, fewer than one-half of FDA managers reported that FDA was making great progress in this area.¹⁹ Specifically, while 80 percent of the managers in our survey reported that additional staff with needed knowledge, skills, and abilities would greatly improve their ability to contribute to FDA's goals and responsibilities, only 43 percent stated that FDA was making great progress recruiting, retaining, and developing its workforce. Furthermore, when asked to identify their top priorities that FDA leadership should address to achieve its goals and responsibilities, FDA managers most commonly identified issues related to human capital management.

In addition, FDA is not strategically managing its efforts in this area. Specifically, while officials told us that its centers and offices are engaging in some strategic human capital efforts, FDA does not have an agencywide strategic human capital plan or an up-to-date workforce plan to coordinate

¹⁹Reported survey responses are estimates. Throughout this report, when we refer to managers reporting to a "great extent" on our 2009 survey of FDA managers, we also include managers responding to a "very great extent." (See app. I for more details.)

these efforts and guide its overall human capital management. In our previous work, we have reported that a strategic approach to marshaling, managing, and maintaining human capital is needed to maximize performance and ensure accountability, and that strategic human capital planning is critical to ensuring that agencies have the talent and skill mix they need to address their current and emerging human capital challenges.²⁰ During meetings with FDA officials, we learned of some human capital planning efforts taking place in its centers and offices. For example, CVM has created its own succession plan, and ORA officials told us that in Fall 2008 they completed a workforce analysis to identify available expertise and gaps in each program area. However, in 2007, an HHS review found that FDA lacked an overarching systemic approach for assessing and improving human capital planning. Since then, FDA has not created an agencywide strategic human capital plan to do this.²¹ FDA has recently issued an agencywide succession plan, which covers plans to address anticipated needs in leadership positions, but the agency has not updated its 2006 workforce plan—a means to identify and address gaps between all current and future workforce needs—which has been out of date for 2 years. Without an updated workforce plan, FDA is lacking an important tool to help systematically determine its staffing needs, for example, which could have helped guide the large hiring efforts of the last 2 years. FDA officials said that one reason the agency has had difficulty in its human capital planning is that the agency lost a great deal of its expertise in this area when HHS assumed human resources processing functions for the whole department, including FDA. In December 2009, FDA officials told us that they had recently initiated an agencywide effort to develop a strategic human capital plan and an updated workforce plan.

Modernizing Information Systems

FDA has reported taking efforts toward modernizing its IT and information management, such as launching new modernization projects, designing policies for investment and project management, and laying the

²⁰GAO, *High-Risk Series: Strategic Human Capital Management*, GAO-03-120 (Washington, D.C.: January 2003); and *Human Capital: Sustained Attention to Strategic Human Capital Management Needed*, GAO-09-632T (Washington, D.C.: Apr. 22, 2009).

²¹On its Web site, the Office of Personnel Management notes that a strategic human capital plan should include the following: a clearly understood strategic direction; customer and stakeholder human capital management goals; strategies for accomplishing those goals; an implementation plan; a communication plan, if needed; and an accountability system. See the following Web address: http://www.opm.gov/HCAAF_RESOURCE_CENTER/RESOURCES.ASP (accessed on 12/14/09).

foundation for improved data systems. In June 2009, we reported that FDA had embarked on a number of relatively new modernization projects and had made some progress to establish important IT management capabilities.²² Specifically, we reported that FDA had established investment and project management policies and, according to an inspector general assessment, was making progress in addressing information security. Similarly, in August 2009, the FDA Science Board reported that FDA had made excellent progress in designing a new IT infrastructure, and that the agency was well-positioned to execute its new IT plans.

While FDA has reported efforts to modernize its IT systems, survey responses from FDA managers and the August 2009 report from the FDA Science Board show that progress is still uneven. In our 2009 survey, 79 percent of FDA managers reported that improving FDA's IT and information management would greatly improve their ability to contribute to FDA's goals and responsibilities, but only 39 percent reported that FDA was making great progress in this area. Furthermore, when we asked FDA managers in our survey to identify the top priorities that FDA leadership should address, improving IT was the third most commonly identified issue. For example, managers providing detailed written responses in our survey noted a lack of direction, focus, and strategic goals for IT at FDA and reported that some FDA systems were ineffective at sharing or reliably reporting data. In addition, the FDA Science Board recently found that FDA faces challenges to modernizing its IT capabilities.²³ In its 2009 report, the Science Board noted that FDA faces several challenges in implementing its new IT systems, including a shortage of expertise in health care data standards and a disconnect between FDA governance and IT execution teams. Additionally, the Science Board concluded that without a detailed IT adoption plan, it was difficult to assess the progress that FDA had made.

Like the Science Board, our June 2009 report on FDA's IT also identified weaknesses in FDA's IT management. Specifically, we reported that significant work remained with regard to building enterprise architecture—that is, the modernization blueprints that describe FDA's

²²GAO, *Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernization Efforts*, [GAO-09-523](#) (Washington, D.C.: June 2, 2009).

²³FDA Science Board, *Subcommittee Review of Information Technology* (Rockville, Md.: August 2009).

operation in terms of business and technology. We also reported that the agency was not strategically managing IT human capital because it had not determined its IT skills needs or analyzed gaps between the skills of its workforce and the future needs of the agency.²⁴ We concluded that without an effective enterprise architecture or strategic IT human capital management, FDA has less assurance that it would be able to modernize effectively and have the appropriate IT staff to effectively implement and support its modernization efforts. We recommended that FDA expeditiously develop a comprehensive IT strategic plan, giving priority to architecture development, and complete key elements of IT human capital planning. In commenting on a draft of the June report, FDA agreed with our recommendations, and, in December 2009, officials told us that they were working to develop an IT strategic plan.

Coordinating Internally and Externally

FDA has reported efforts to enhance coordination both within the agency and with other agencies and experts. However, in our survey, a minority of FDA managers reported that FDA was making great progress in addressing this challenge. For example, FDA reported that all of its centers and offices are in close contact with the agency's offices located in India and China to share expertise and support. FDA also has reported that CDRH and ORA have teamed up to offer training on radiation safety and awareness to ORA imports officers. As it relates to external coordination, in March 2009, the President created the Food Safety Working Group (FSWG) to improve food safety and assess performance metrics. FDA participates in this group, along with the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), the Centers for Disease Control and Prevention (CDC), and other federal agencies. In another example of external coordination, ORA reported that it is involved in collaborations with agencies, such as the Department of Defense and the Department of Homeland Security, in areas such as sharing information on food protection. Also, FDA told us that during the 2009 foodborne illness outbreak linked to peanut products, FDA used an incident command structure to more effectively work with other federal agencies, state regulators, and industry members to identify the source of the outbreak.

While these recent efforts are encouraging, a minority of FDA managers in our survey reported that FDA was making great progress in the area of coordination. Specifically, while 70 percent of FDA managers in our

²⁴[GAO-09-523](#).

survey reported that better internal coordination and communication would greatly improve their ability to contribute to FDA's goals and responsibilities, only 28 percent reported that FDA was making great progress in this area. Furthermore, we asked FDA managers in our survey to identify the top priorities that FDA leadership should address to achieve agency goals and responsibilities, and the second most commonly identified issue was improving coordination within FDA. For example, in detailed written comments in our survey, some managers noted that agency leaders should consult with the centers more frequently to obtain input regarding performance, budgetary needs, and other administrative initiatives. Other managers noted that better coordination among FDA's centers could increase effectiveness and decrease redundancy. As it relates to coordinating with other federal agencies, we found similar results: While 49 percent of FDA managers reported in our survey that better coordination and communication with other federal governmental entities would greatly improve their ability to contribute to FDA's goals and responsibilities, only 19 percent of survey respondents reported that they believed the agency was making great progress in this area.

Keeping Pace with Scientific Advances

FDA has reported efforts to keep pace with scientific advances, but a minority of FDA managers reported in our survey that the agency was making great progress. FDA has reported some efforts. For example, FDA reported that in May 2008, the agency created the Office of the Chief Scientist, and, in May 2009, added more responsibilities to the office to signal a new emphasis on regulatory science. FDA also told us they had plans to identify major scientific crosscutting opportunities across its centers and to collaborate with other government agencies, such as the National Institutes of Health, and with research universities. Additionally, according to FDA, NCTR is establishing two new research facilities to address emerging areas of science, such as nanotechnology. However, while 67 percent of FDA managers in our survey reported that updated scientific technologies or other tools would greatly help them to contribute to FDA's goals and responsibilities, only 36 percent of managers reported that they believed FDA was making great progress in keeping pace with scientific advances. For example, in some written comments in our survey, some managers stressed the need for increasing funding, resources, and technology for science.

Communicating with the Public

FDA also has reported undertaking efforts to improve its communication with the public, and a majority of FDA managers indicated in our survey that the agency was making great progress in this area. FDA reported that in September 2009, it released a strategic plan on risk communication that lays out the agency's plans for disseminating information to the public and

overseeing industry communications. Similarly, in June 2009, the agency reported that it had created a Transparency Task Force to help improve the availability and quality of public information. Additionally, during the 2008-2009 foodborne illness outbreak related to peanut products, FDA used social media and internet tools, such as a blog hosted by CFSAN, to inform the public of product recalls. In our survey, FDA managers reported that communication was an area of improvement: Fifty-three percent of FDA managers in our survey reported that they believed FDA was making great progress in communicating product safety information to the public. For example, in their detailed written comments in our survey, some managers noted that FDA was receiving positive comments on the amount and timeliness of information provided to the public through the agency's new Web site design. These efforts to increase transparency and reach out to the public hold promise, but it is too soon to tell their long-term effect in improving public communication.

FDA's Annual Performance Measures Are Only Partially Results-Oriented

FDA's 48 annual performance measures for fiscal year 2010 are only partially results-oriented because they do not adhere to some key characteristics we identified from our work on government performance issues that could help decision makers effectively gauge agency progress. Of these characteristics, FDA generally incorporated some characteristics into its fiscal year 2010 performance measures—that is, FDA linked its measures to agency and department goals, showed baseline and trend data for past performance, included explanatory information, and included intermediate measures to show progress toward longer term goals. However, FDA's measures do not incorporate other characteristics we identified. Specifically, FDA's measures do not focus on public health outcomes, address important dimensions of the agency's performance, identify projected target levels of performance for multiyear goals, or fully address identified management challenges. Without such characteristics, FDA is missing opportunities to guide decisions and assess actual performance.

FDA's Performance Measures Incorporate Some Key Characteristics to Improve Their Usefulness to Decision Makers

FDA has incorporated some selected characteristics of results-oriented performance measures that can improve the usefulness of such measures to decision makers. In our review of the fiscal year 2010 budget request for FDA, we found that the agency incorporated the following characteristics in its performance measures:

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- A linkage to agency and department goals, which can help clarify the relationship between yearly measures and longer term goals and objectives. Specifically, FDA linked each of its 48 annual performance measures to 1 of the agency's 14 objectives, which in turn link to FDA's and HHS's strategic goals. For example, FDA linked 1 of its measures—the number of high-risk animal drug and feed inspections—with the agency's strategic goal on oversight of manufactured products.
 - Inclusion of explanatory information on each of its performance measures, which can help provide a rationale for the measure or inform readers of data sources. For example, in its explanatory notes on its performance measure to increase laboratory capacity in the event of a terrorist attack on the food supply, FDA noted that it gains this increased capacity by awarding cooperative agreements to states with applicable chemistry and radiological laboratories, which receive funding for training and testing.
 - Showing baseline and trend data for each of its performance measures, which can help decision makers draw conclusions about whether the performance measures are reasonable and appropriate. Our review of the fiscal year 2010 budget request found that it generally lists up to 5 years of baseline and trend data for the agency's performance measures, except for newer measures where trend data are not yet available.
 - Using intermediate performance measures, which can help show progress toward intended results. For instance, when it may take years before an agency sees the results of its programs, intermediate measures can provide information on interim results. For example, one of FDA's performance measures is to develop risk assessment methods and build biological dose-response models in support of food protection. In fiscal year 2008, the target for this measure was to develop tests that could determine the presence of the toxin ricin. In fiscal year 2010, the target was to develop rapid-detection toolkits for foodborne pathogens, applicable to fresh produce and usable in the field.

FDA's Performance Measures Lack Other Key Characteristics of Results-Oriented Measures

FDA's fiscal year 2010 performance measures lack other selected characteristics of results-oriented measures. First, most of FDA's performance measures do not focus on outcomes. Instead, 38 of FDA's 48 performance measures are output measures—which provide information on products or services delivered—or efficiency measures—which provide information on the relationship between the agency's outputs and the resources used to produce them. Only 10 are outcome measures that provide information on the actual public health results of FDA's work that

are of interest to the public. Table 2 provides information on the number and type of FDA’s 48 performance measures for fiscal year 2010 by center and office. Specifically, when examining these performance measures across FDA’s centers and offices, we found that none of the annual performance measures for five centers and offices—the Center for Biologics Evaluation and Research (CBER), CDER, CVM, NCTR, and the Office of the Commissioner (OC)—are outcome measures. For example, both of CVM’s annual performance measures are outputs that tally the number of new animal drug applications the center reviewed. While reviewing new drug applications is an important part of CVM’s work, these tallies do not provide information on the extent to which the center has accomplished the broader public health goals that those reviews of drug applications are intended to achieve. Only two centers—CDRH and CFSAN—focus more heavily on outcomes: All of CDRH’s five measures and two of CFSAN’s three measures are outcome measures. For example, one of CDRH’s outcome measures tracks the percentage of domestic mammography facilities that meet certain inspection standards.²⁵ In our survey of FDA managers, several respondents provided detailed written comments indicating a need for more outcome measures. For example, one manager commented that there was a great need for agency goals to go beyond providing tallies and information on tasks completed. Another manager suggested that FDA establish long-term goals and outcome measures that reflect agency priorities.

Table 2: Number of FDA’s Fiscal Year 2010 Performance Measures, by Center and Office

Center/Office	Output and efficiency measures	Outcome measures	Total measures
CBER	6	0	6
CDER	8	0	8
CDRH	0	5	5
CFSAN	1	2	3
CVM	2	0	2
NCTR	6	0	6

²⁵This measure’s target for fiscal years 2007 through 2010 is for 97 percent of facilities to meet those standards, and FDA reports meeting that target for all years in which data are available.

Center/Office	Output and efficiency measures	Outcome measures	Total measures
OC	3	0	3
ORA	12	3	15
Total	38	10	48

Source: GAO analysis of FDA data.

FDA's 2010 performance measures also do not address important dimensions of the agency's performance, such as addressing all major strategic objectives, which is another key characteristic of results-oriented measures. The performance measures listed in the fiscal year 2010 budget request do not fully address many of FDA's main strategic objectives. (See app. II for a crosswalk of FDA's strategic goals and objectives to fiscal year 2010 performance measures.) Specifically, of the 14 objectives in FDA's 2007 Strategic Action Plan, 5 do not have associated performance measures. FDA's performance measures are clustered under 2 of FDA's 4 strategic goals related to increasing access to new medical and food products and improving the quality and safety of manufactured products and the supply chain.

In addition to not focusing on outcomes and to omitting important dimensions of agency performance, FDA's performance measures also do not provide projected target levels of performance beyond the immediate budget year for its multiyear goals—another characteristic of results-oriented measures. Where appropriate, an agency should convey what it expects to achieve in the long term by including multiyear performance goals. FDA's lack of such measures deprives stakeholders of an indication of the longer term progress the agency expects to make.

Finally, FDA's annual performance measures for fiscal year 2010 do not address some mission-critical management challenges. Our review of the fiscal year 2010 budget request for FDA found that the agency does not have measures related to its management challenges to recruit, retain, and develop its workforce or to communicate safety information to the public. In addition, its performance measures for 2010 only partially address the management challenge of coordinating internally and externally. For example, we found several performance measures relating to coordinating internally and externally, but none of them specifically measure performance to improve FDA's internal coordination.

Without results-oriented performance measures, FDA has less information available to effectively measure the agency's progress toward meeting its

intended goals. In past work, we have acknowledged that such measures are sometimes difficult to develop.²⁶ For example, we have reported that federal managers face challenges developing outcome measures when a program or line of effort was not easily quantifiable, and that it can be difficult to distinguish the impact of a particular federal program from the impact of other programs and factors, thus making it difficult to attribute specific program performance to results. Despite these difficulties, FDA officials acknowledged that they need more representative, outcome-oriented measures, and they said that the agency is working to develop them. Specifically, officials told us that the agency hopes to create between one and three performance measures for each of its objectives that will focus more on public-health-related outcomes. For example, officials from CFSAN noted that they are trying to create an outcome measure related to shortening the amount of time it takes the agency to accurately identify pathogens associated with a foodborne illness outbreak. FDA officials told us that some of these changes may be reflected in the agency's fiscal year 2011 and future year budget requests.

Although Some Progress Has Been Made, Alignment of Activities and Resources to Strategic Goals Is Unclear at the Center and Office Level

FDA has taken steps across the agency to align its activities and resources to the strategic goals in its Strategic Action Plan, but has not clearly demonstrated alignment at the center and office level. In our previous work, we have noted that sound planning is not enough to ensure success, and that an organization's activities and resources must be aligned to help it achieve its goals and mission.²⁷ In developing its Strategic Action Plan, FDA aligned the three areas of regulatory activities that are central to the agency's mission—pre-market review, production oversight, and post-market surveillance—to three of the agency's four strategic goals in its plan:

- *Pre-market review* covers FDA's activities to approve, or clear for marketing, new medical products and develop regulations or guidance for food and medical product safety, among other things. In its Strategic Action Plan, FDA aligned these activities with its strategic goal to increase access to new medical and food products.
- *Production oversight* covers FDA's activities related to inspections of food and medical product facilities, import entry review, investigations

²⁶ [GAO-04-38](#).

²⁷ [GAO/GGD-96-118](#).

and recalls, and enforcement activities, among other things. In its Strategic Action Plan, FDA aligned these activities with its strategic goal to improve the quality and safety of manufactured products and the supply chain.

- *Post-market surveillance* covers FDA’s activities related to surveillance of products that FDA has approved or cleared for marketing, including adverse event report processing, advertising oversight, and risk communication research. In its Strategic Action Plan, FDA aligned these activities with its strategic goal to improve patient and consumer safety.

FDA has placed a variety of other activities under its strategic goal to strengthen FDA for today and tomorrow, including policy development, administration and systems, and external relations, among others. In aligning its strategic goals to these activities, FDA intends to provide continuity across the wide range of activities taking place across its centers and offices, each of which has a unique organizational structure and scope of responsibility.

In addition to aligning its main activities to goals in the Strategic Action Plan, FDA also uses employee performance plans to help ensure that its employees’ activities are linked to the agency’s strategic goals. Performance plans for FDA employees, including senior executives, describe an individual’s responsibilities for the year, and HHS specifies that for all HHS managers and employees, elements in those plans must link to HHS or FDA goals. For example, one FDA senior executive’s fiscal year 2008 performance plan we reviewed included a responsibility to identify a certain number of candidates for FDA’s fellowship program. This responsibility was explicitly linked to FDA’s strategic goals in pre-market review and post-market surveillance in that manager’s performance plan. We previously reported that such linkages help create a “line of sight” between individual performance and organizational success,²⁸ and FDA officials told us that this practice is improving employees’ understanding of their work in the larger context of the agency.

While FDA has taken steps through its Strategic Action Plan and individual performance plans to align activities with goals across the agency, FDA has not clearly demonstrated alignment of activities to goals within its centers and offices. Currently, only four of FDA’s eight centers and offices

²⁸ [GAO-04-38](#).

we reviewed clearly demonstrated that their activities aligned to FDA's goals through their documentation. Each of FDA's main centers and offices has its own focus and responsibilities and conducts activities to meet those responsibilities in a variety of ways. Therefore, it is important for FDA to link these activities to FDA's overall goals to ensure agencywide alignment. While officials told us that their activities are generally linked to goals, they also noted that those links are not always clear. Furthermore, our review of documentation on FDA's program activities showed that only four of the eight centers and offices we reviewed—CDER, CDRH, CVM, and NCTR—provided clear links between their activities and FDA's goals that can help congressional decision makers understand how the agency intends to accomplish its goals. Specifically, part of CDER, CDRH, and CVM's main program activities in the fiscal year 2010 budget request for FDA included the areas of pre-market review and post-market surveillance, which correspond to 2 of FDA's strategic goals. Similarly, NCTR used its strategic plan to explicitly link its main activities, including personalized nutrition and medicine and food protection, to FDA's goals.

In contrast to CDER, CDRH, CVM, and NCTR, the other four centers and offices we reviewed—CBER, CFSAN, OC, and ORA—did not clearly demonstrate alignment of their program activities to FDA's goals through their documentation. For example, the fiscal year 2010 budget request for FDA noted that CFSAN's activities fall into four areas—ensuring food protection, improving nutrition, improving dietary supplement safety, and improving cosmetic safety—and did not explain the relationship between these four areas and FDA's goals. FDA officials told us that CFSAN's activities were guided by FDA's 2007 Food Protection Plan and, more recently, the administration's newly formed FSWG, and that both are similar to FDA's Strategic Action Plan in their organization around pre-market review, production oversight, and post-market surveillance. However, neither the Food Protection Plan nor FSWG covers CFSAN's responsibilities related to nutrition, dietary supplements, and cosmetics. The relationship between FDA's activities and its goals was more clear in the past. Specifically, the fiscal year 2008 budget request for FDA did include some information on the relationship between each center's and office's program activities and FDA's strategic goals, but officials told us that this information was not included in the budget request in fiscal years 2009 and 2010 to make the document more concise. While a concise presentation is important, the lack of clear alignment between activities and goals hinders Congress's ability to assess the likelihood of FDA's success. FDA officials told us that the agency is working to implement a new performance management system that will improve transparency,

accountability, and alignment of activities to goals, and is piloting the new system in offices across the agency.

FDA has worked to align its resources to its strategic goals by assigning dollar amounts of requested resources to many of its performance measures. We reported that accurately depicting how funding is allocated to achieve goals is a critical step in defining the performance consequences of budgetary decisions.²⁹ To provide information to Congress on the resources needed to achieve intended results, agencies—following OMB³⁰ guidance—should link the resources requested for each program to expected levels of performance, and, at a minimum, resources should be aligned at the program level and, if possible, to an agency’s annual performance measures.³¹ FDA has assigned dollar amounts to each of its performance measures in the fiscal years 2009 and 2010 budget requests for FDA. Specifically, in fiscal year 2010, FDA has assigned about \$3.1 billion of its total requested budget of about \$3.2 billion to many of its performance measures in the budget request. For example, in that request, FDA assigned an amount of \$341 million to its performance measure on high-risk food inspections and \$224 million to its performance measure on establishing and maintaining accreditation for ORA laboratories.

However, clear linkages between FDA’s resources and its goals are still incomplete. First, as we have previously noted in our discussion of FDA’s performance measures, not all important dimensions of FDA’s performance are addressed by the agency’s fiscal year 2010 measures. FDA officials have told us that the dollar amounts assigned to performance measures in the budget are incomplete because some of FDA’s work is related to efforts not covered by its current set of performance measures. Officials also told us that they are working to revise the budget request to provide greater transparency in how FDA allocates resources by performance goals.

²⁹GAO, *Performance Budgeting: Initial Experiences Under the Results Act in Linking Plans with Budgets*, GAO/AIMD/GGD-99-67 (Washington, D.C.: Apr. 12, 1999).

³⁰OMB is responsible for receiving and reviewing agencies’ strategic plans, annual performance plans, and annual performance reports. To improve the quality and consistency of the documents, OMB issues annual guidance to agencies for their preparation, including guidelines on format, required elements, and submission deadlines.

³¹OMB Cir. No. A-11, Sec. 220, p. 1 (2009).

In addition, with the exception of NCTR and CVM, officials from FDA's centers and offices told us that they do not track workload—as measured through the agency's various employee time reporting systems—by strategic goals, which hinders FDA's and Congress's ability to effectively understand the link between such costs and outcomes. Specifically, while more than one-half of FDA's budgetary obligations relates to personnel costs, only two of the centers and offices we reviewed—NCTR and CVM—have established a means, through their employee time reporting systems, to allow effective tracking of employees' work back to FDA's strategic goals. NCTR tracks employee's time according to each of its research projects. Projects each then link to the center's and agency's strategic goals. In addition, CVM has a time reporting system that tracks 100 percent of its employees' work time to specific activities, which map to FDA's goals. While the other centers and ORA track employees' work time to varying degrees, which can provide useful management information, officials told us that they do not track that time to FDA's goals, which limits management's ability to understand how employees' time, and therefore the bulk of FDA's resources, is used in support of FDA's goals.

We have recently reported similar limitations in FDA's tracking of resources in other areas. In our 2008 review of FDA's oversight of fresh produce safety, we reported that FDA has not consistently and reliably tracked its spending on oversight of fresh produce.³² Furthermore, in our 2009 review of the resources supporting FDA's medical product oversight, we reported that FDA could not provide data showing its workload and accomplishments in some areas, depriving the agency of basic data needed for managing its programs.³³ To address this problem, we recommended that FDA take steps to establish a comprehensive and reliable basis for substantiating the agency's resource needs. FDA agreed with our recommendations and told us in December 2009 that they awarded a contract to help them estimate the resources needed to fulfill their responsibilities, which could, among other things, help FDA better link their resources to agency goals. The current lack of clear linkages between FDA's resources and its goals limits the ability of congressional decision makers to understand how spending is affecting outcomes and whether

³²[GAO-08-1047](#).

³³GAO, *Food and Drug Administration: FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs*, [GAO-09-581](#) (Washington, D.C.: June 19, 2009).

the agency should be allocating its resources differently to be more effective at achieving its regulatory mission.

About One-half or Fewer FDA Managers in Our Survey Reported Extensive Use of Performance Information and Application of Practices to Encourage Its Use

In our 2009 survey, about one-third to one-half of FDA managers reported using performance information to a great extent to make management decisions, with the extent varying depending on the type of management decision. These results did not differ significantly from our 2007 survey results for all federal managers, when we concluded that more progress was needed for agencies to further integrate information about program performance into their decision making. When we surveyed agency managers on practices to improve the use of performance information, one-half or fewer of FDA managers reported extensive application of practices, such as demonstrating management commitment, to encourage the use of performance information, or reported having had training in the use of performance information.

About One-third to One-half of FDA Managers Reported Using Performance Information Extensively, Depending on the Type of Management Decision

In our 2009 survey, about one-third to one-half of FDA managers reported using performance information to a great extent for making selected management decisions, with the extent depending on the particular type of management decision.³⁴ As we have observed in our prior work, agencies fully realize the benefit of collecting and measuring performance information only when this information is used to support management planning and decision making.³⁵ FDA managers answered seven questions in our survey related to the extent of their use of performance information to make selected management decisions, and, depending on the question, 33 percent to 53 percent of FDA managers reported great use of performance information to make particular types of decisions.³⁶ (See fig. 3.) For example, 47 percent of FDA managers reported in our survey that

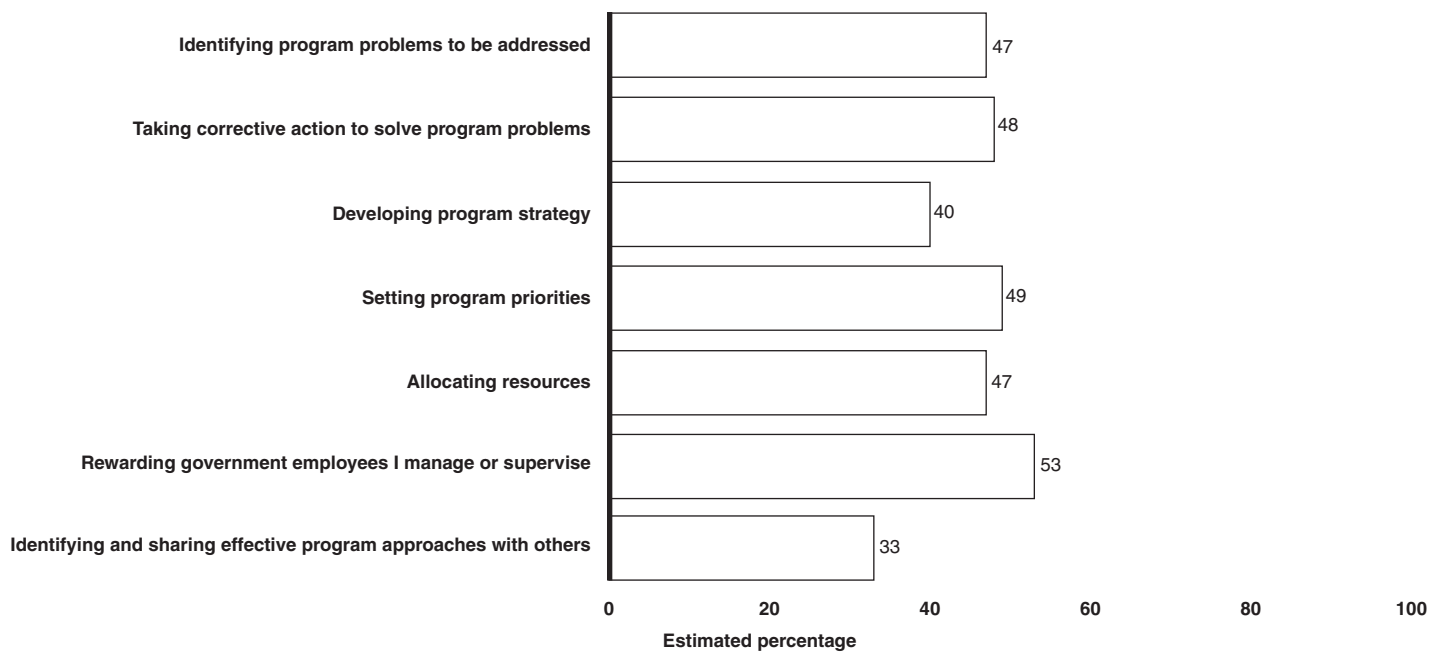
³⁴Reported survey responses are estimates. Throughout this report, when we refer to managers reporting a “great extent” on our 2009 survey of FDA managers, we are also including managers responding “very great extent.” (See app. I for more details.)

³⁵[GAO-05-927](#).

³⁶In our prior work, we identified the following four types of management decisions for which federal managers can use performance information to improve programs and results: (1) identifying problems and taking corrective action; (2) developing strategy and allocating resources; (3) recognizing and rewarding performance; and (4) identifying and sharing effective approaches. We reviewed seven questions in our survey related to these four types of management decisions.

they used performance information to a great extent when identifying program problems to be addressed. The percentage of FDA managers reporting extensive use of performance information did not differ significantly from the percentage of all federal managers answering the same questions in our 2007 survey. In our testimony on that 2007 survey, we concluded that progress was still needed for agencies to further integrate information about program performance into their decision making.³⁷

Figure 3: Percentage of FDA Managers Reporting Great Use of Performance Information for Selected Management Decisions



Source: GAO.

Note: Percentages represent survey responses of a “great extent” and “very great extent.” All percentage estimates in this figure have a margin of error of plus or minus 10 percentage points or less.

In responding to our 2009 survey, FDA managers provided detailed written examples of how they used performance information to make management decisions. For example, FDA managers told us that they used

³⁷ [GAO-08-1026T](#).

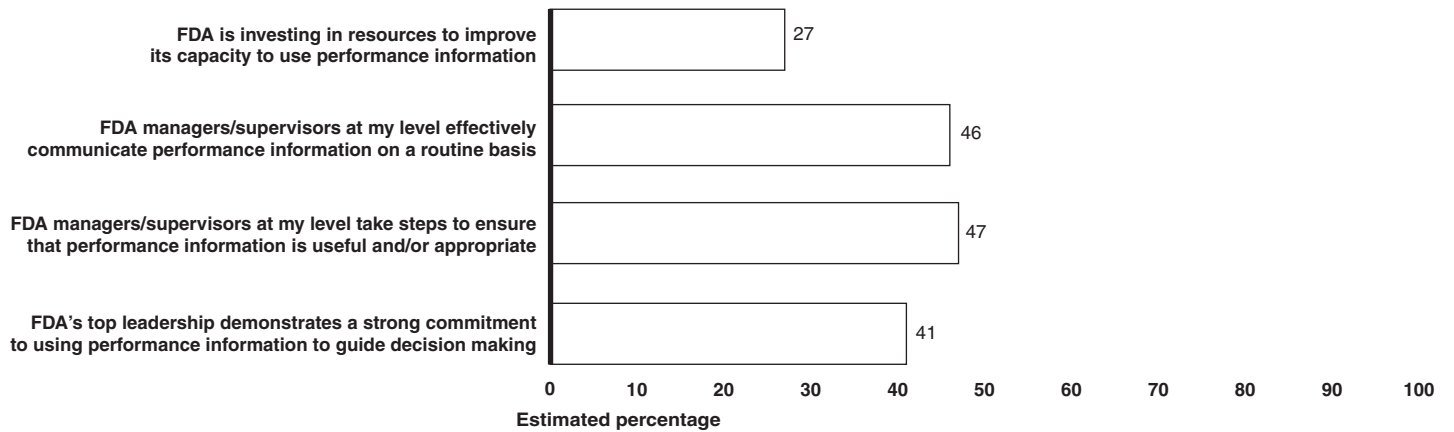
-
- data on progress toward goals to identify program areas in need of closer inspection;
 - information on the quality, productivity, and relevance of research output to allocate research resources;
 - employee performance information to grant awards, bonuses, and promotions; and
 - productivity reports from specific programs to identify effective program approaches to implement FDA's hiring initiative in 2008 and 2009 and share them within and outside the agency.

Less than One-half of FDA Managers Reported Extensive Application of Practices or Having Received Training to Encourage Use of Performance Information

In our 2009 survey about one-quarter to one-half of FDA managers reported extensive application of practices, such as demonstrating management commitment, to encourage the use of performance information. FDA managers' reported use of performance information was not significantly different from the results of our 2007 survey of all federal managers, when we reported that progress was still needed. Therefore, we reviewed FDA managers' survey responses on agency use of practices to help make progress in this area. As we have previously reported, agencies can benefit from applying practices that can enhance the use of performance information for policy and program decisions aimed at improving results.³⁸ In selected survey questions, about 27 percent to 47 percent of FDA managers reported that these practices were applied to a great extent at FDA, depending on the practice. (See fig. 4.) For example, 41 percent of FDA managers agreed to a great extent with the statement that FDA's top leadership demonstrates a strong commitment to using performance information to guide decision making. These estimates are not significantly different from what we found in 2007 when we surveyed managers across the federal government on their application of practices to encourage the use of performance information.

³⁸See [GAO-05-927](#). We focused on the following four practices: (1) demonstrating management commitment; (2) improving the usefulness of performance information to better meet management's needs; (3) frequently and effectively communicating performance information within the agency; and (4) developing agency capacity to effectively use performance information. We did not use the survey to review one of our identified practices on aligning agencywide goals, objectives, and measures, because our second and third research objectives examined this topic using other research methods.

Figure 4: Percentage of FDA Managers Reporting Extensive Application of Selected Practices to Encourage the Use of Performance Information

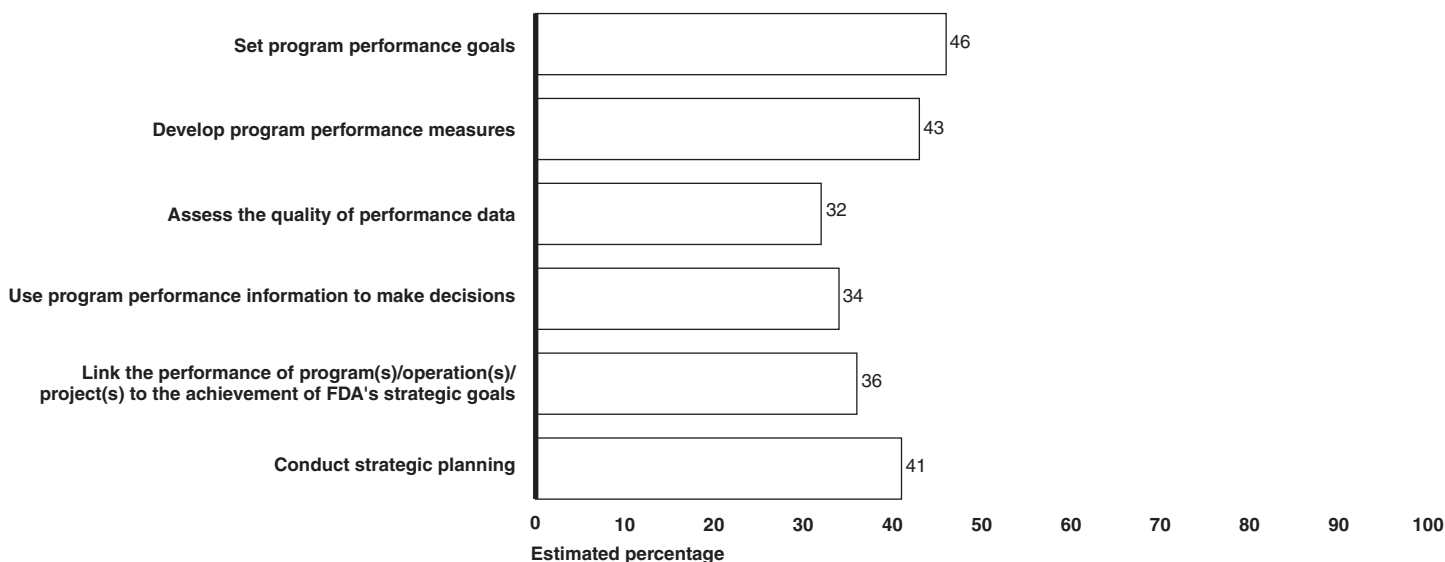


Source: GAO.

Note: Percentages represent survey responses of a “great extent” and “very great extent.” All percentage estimates in this figure have a margin of error of plus or minus 10 percentage points or less.

One way to develop agency capacity to use performance information is through training, but fewer than one-half of FDA managers reported receiving such training. Our review of responses to our 2009 survey questions related to developing agency capacity to use performance information shows about one-third of FDA managers reported receiving three types of training related to performance information and slightly more reported receiving three other types. (See fig. 5.) For example, 34 percent of FDA managers reported in 2009 that they had received training in using performance information to make decisions. FDA’s weakness in this area hinders its ability to build capacity and ensure that performance information is easily collected, communicated, and analyzed.

Figure 5: Percentage of FDA Managers Reporting That They Received Six Types of Training Related to Performance Information



Source: GAO.

Note: All percentage estimates in this figure have a margin of error of plus or minus 10 percentage points or less.

Training is important because, as we have noted in prior work, managers must understand how the performance information they gather can be used to provide insight into the factors that impede or contribute to program successes; assess the effect of the program; or help explain the linkages between program inputs, activities, outputs, and outcomes.³⁹ In earlier work, we found a positive relationship between agencies providing training on setting program performance goals and the use of performance information when setting or revising them.⁴⁰ In that work, we recommended that OMB work with agencies to ensure that they were making adequate investments in training on performance planning and measurement, with a particular emphasis on how to use performance information to improve program performance. OMB has not acted on this recommendation. FDA officials told us in December 2009 that they are in the planning stages of developing performance budget training, which will

³⁹ GAO-08-1026T.

⁴⁰ GAO-04-38.

include a module on performance measure development suitable for program managers, but the agency does not have a timeline for this training.

Conclusions

Along with concerns expressed by others, our work examining strategic planning and management at FDA indicates that the agency is facing significant management challenges that could affect its ability to protect Americans from unsafe and ineffective products. FDA is aware of its challenges and has taken steps to address them, but the agency still does not fully use practices for effective strategic planning and management. Notably, FDA's lack of a strategic human capital plan and an up-to-date workforce plan limits the agency's ability to effectively recruit, hire, manage, and maintain the highly skilled workforce it needs to skillfully execute its mission. In addition, FDA's performance measures do not include some key characteristics we reviewed that can help provide decision makers with useful information on agency results. Specifically, FDA's measures do not focus on outcomes, address important dimensions of agency performance, identify projected target levels of performance for multiyear goals, or fully address identified management challenges. Without these characteristics, FDA may not be collecting all of the information it needs to make good decisions on the best strategies and resources to employ to fulfill its mission. Furthermore, four of the eight centers and offices we reviewed did not clearly demonstrate alignment of program activities to goals through their documentation, which can hinder congressional decision makers' ability to understand how the agency intends to accomplish its goals. Similarly, linkages between resources and goals at FDA are incomplete for two reasons: Not all important dimensions of FDA's performance are addressed by the agency's existing performance measures, and several of FDA's centers and offices do not clearly track their workload according to strategic goals. The absence of such linkages hinders FDA's and congressional decision makers' ability to effectively understand the link between costs and outcomes. Finally, our 2009 survey shows that fewer than one-half of FDA managers reported receiving training on the use of performance information. Such training could help FDA managers—and thus FDA—make improvements in the overall use of such information.

Recommendations for Executive Action

To help the agency more strategically manage its operations, we are making five recommendations to the Commissioner of the Food and Drug Administration.

- To more strategically manage its human capital, we recommend that the Commissioner of FDA develop a strategic human capital plan and issue an updated workforce plan.
- To help decision makers more effectively gauge agency progress, we recommend that the Commissioner of FDA work to make FDA's performance measures more results-oriented.
- To more clearly demonstrate the alignment of activities to strategic goals, we recommend that the Commissioner of FDA direct each of the agency's main centers and offices to clearly align their program activities to FDA's strategic goals in documents, such as the budget request or center- and office-level documents.
- To more clearly demonstrate alignment of resources to strategic goals, once FDA creates a more results-oriented set of performance measures, we recommend that the Commissioner of FDA direct FDA's centers and offices to track their workload by strategic goals.
- To encourage greater use of performance information, we recommend that the Commissioner of FDA work to build FDA's capacity to collect and analyze performance information by expanding training for managers on topics related to performance information.

Agency Comments and Our Evaluation

We provided a draft of this report to the Department of Health and Human Services for review, and HHS provided written comments, which are reprinted in appendix III. HHS noted that the Food and Drug Administration agreed with our recommendations and that FDA is in the process of implementing them. The department also noted that our report provides a baseline of past strategies and management practices against which FDA's leadership can measure its progress.

HHS also provided us with additional information in its written comments related to FDA's efforts to implement each of the recommendations we made in our draft report. Specifically, in regards to our recommendations that FDA:

-
- *Develop a strategic human capital plan and issue an updated workforce plan:* HHS noted that FDA has recently awarded a contract to support development of these plans.
 - *Make its performance measures more results-oriented:* HHS stated that FDA is developing a new performance tracking and management system. The department also noted that FDA is working to improve and expand the performance measures to be included in the fiscal year 2011 budget request for FDA.
 - *Clearly align its program activities to its strategic goals:* HHS indicated that FDA will include a new table in the fiscal year 2011 budget request that links each subprogram area to FDA's strategic objectives.
 - *Track workload by strategic goals:* HHS noted that FDA has awarded a contract to help develop its ability to estimate its resource needs. The department stated that the workload models produced by this project will serve as a foundation for further efforts to link workload to the agency's goals.
 - *Expand training on topics related to performance information:* HHS noted that FDA is developing a training plan and a Statement of Work related to this issue. The department stated that FDA plans to develop or purchase training modules and pilot them in fiscal year 2010, with the training expected to be made available in fiscal year 2011.

In its written comments, HHS also noted that language in our draft report comparing our 2009 survey results on training related to performance information with similar results in our 2007 governmentwide survey was not valid because the response options for the two surveys differed. We agree and have removed that comparison from our final report. However, because training can increase the use of performance information and fewer than one-half of FDA managers reported receiving it, our conclusion remains unchanged—that training is needed to improve FDA managers' capacity to use performance information. FDA agreed with the resulting recommendation.

HHS also provided us with technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Commissioner of the Food and Drug Administration, and other interested parties. The report also will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov or Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.



Lisa Shames
Director, Natural Resources and Environment



Marcia Crosse
Director, Health Care

Appendix I: Objectives, Scope, and Methodology

In this report, we examined the extent to which (1) the Food and Drug Administration's (FDA) 2007 Strategic Action Plan¹ 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 reported using performance information in decision making and applying key practices to encourage that use. To address part of our work for our first and fourth objectives, we administered a Web-based survey on performance and management issues to a sample of managers at FDA from June through August, 2009. For the purposes of this report, we defined managers and supervisors as those employees at or above the GS-13 level as indicated in FDA's data submissions to the Office of Personnel Management (OPM), or those of equivalent rank in other pay systems, including Public Health Service Commissioned Corps Officers. When we use the term "managers," we refer to both managers and supervisors. The sample was a stratified, random, probability sample of 437 persons from a population of 1,276 FDA managers, drawn from data provided by the agency in May 2009. Over 300 respondents, or about 70 percent of our sample, completed the questionnaire, as indicated by the respondent. The Web-based survey included a final question asking respondents if they were ready to submit their final and official responses to GAO. We did not use survey responses in our analysis unless respondents indicated that their survey was complete. The response rate across the eight FDA centers and offices we surveyed ranged from 58 percent to 83 percent.

The survey was designed to obtain the observations and perceptions of respondents on the following: (1) various aspects of results-oriented management topics, such as the presence and use of performance measures, hindrances to measuring performance and using performance information, and agency climate, and (2) management challenges and priorities at FDA. Most of the questions on the survey were closed-ended, meaning that, depending on the particular item, respondents indicated their responses on the following scale: "no extent," "small extent," "moderate extent," "great extent," or "very great extent." On most questions, respondents also had an option of choosing the response category "no basis to judge/not applicable." When reporting the survey results, we generally reported all responses indicating either "great extent"

¹Department of Health and Human Services, U.S. Food and Drug Administration, *FDA Strategic Action Plan: Charting Our Course for the Future* (Rockville, Md.: Fall 2007).

or “very great extent” as “great extent” or “extensive.” We also asked some open-ended questions so that FDA managers could provide detailed written comments, such as examples of how they used performance information to make decisions, and more context from their point of view to their closed-ended answers.

Most questions in the survey had previously been asked of a sample of federal managers in four earlier GAO surveys. The earliest survey was conducted between November 1996 and January 1997 as part of the work we did in response to a Government Performance and Results Act of 1993² requirement that we report on governmentwide implementation of the act. The second survey (conducted between January and August, 2000), the third survey (conducted between June and August, 2003), and the fourth survey (conducted between October 2007 and January 2008) were designed to update the results from each of the previous surveys.³ The 2000 and 2007 surveys, unlike the other two surveys, were designed to support analysis of the data at the department and agency levels as well as provide governmentwide data. To administer the survey, we sent an e-mail to members of the sample notifying them of the survey’s availability on the GAO Web site and included instructions on how to access and complete the survey. Members of the sample who did not respond were sent up to three subsequent reminders asking them to participate in the survey.

The overall survey results are generalizable to the full population of FDA managers, as described in our definition. Our sample also allowed us to generalize results for managers in the following three smaller groupings at FDA: (1) the Center for Food Safety and Applied Nutrition; (2) the Office of Regulatory Affairs; and (3) the medical product centers, comprised of the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological

²Pub. L. No. 103-62 § 8(b), 107 Stat. 285, 295.

³For information on the design, administration, and results of the four earlier surveys, see GAO, *Government Performance: Lessons Learned for the Next Administration on Using Performance Information to Improve Results*, [GAO-08-1026T](#) (Washington, D.C.: July 24, 2008); *Government Performance: 2007 Federal Managers Survey on Performance and Management Issues, an E-supplement to GAO-08-1026T*, [GAO-08-1036SP](#) (Washington, D.C.: July 2008); *Results-Oriented Government: GPRA Has Established a Solid Foundation for Achieving Greater Results*, [GAO-04-38](#) (Washington, D.C.: Mar. 10, 2004); *Managing for Results: Federal Managers’ Views on Key Management Issues Vary Widely Across Agencies*, [GAO-01-592](#) (Washington, D.C.: May 25, 2001); and *The Government Performance and Results Act: 1997 Governmentwide Implementation Will Be Uneven*, [GAO/GGD-97-109](#) (Washington, D.C.: June 2, 1997).

Health (CDRH).⁴ To produce generalizable results, we based our estimates on all respondents who completed our survey, including those not answering a particular question or those providing the following answer: “no basis to judge/not applicable.” We also included a question on whether respondents had performance measures for their program(s)/operation(s)/project(s). If respondents answered “no” or “don’t know” to this question or did not answer it, we placed them in the “no answer” category for subsequent questions on their use of performance information.⁵ In both cases, this is the same method that we used in our previous governmentwide surveys on performance and management issues. The responses of each eligible sample member who provided a useable questionnaire were weighted in the analyses to account statistically for all members of the population. We created weights for each survey respondent to account for unequal probabilities of selection and various unit response rates among the survey strata. To do this, we first calculated a base weight within each survey stratum, which was the ratio of the population and the sample sizes within that stratum. We then applied an adjustment factor within each stratum to account for nonrespondents in the sample and to ensure accurate representations of known strata population totals. We conducted an analysis designed to identify whether results from the survey contained evidence of bias caused by members of the survey who did not provide responses. We compared weighted response rates and estimates from survey respondents with survey nonrespondents for several demographic variables. We did not identify evidence of significant bias in estimates of all FDA managers or estimates for managers in the three smaller groupings at FDA. Our accompanying e-supplement to this report provides information on the survey, including the weighted percentage estimates for all FDA managers and broken out into the three smaller groupings at FDA.⁶ All weighted percentage estimates have a margin of error of 10 percentage points or less. We did not include data on demographic questions or on open-ended questions to preserve respondent confidentiality.

⁴Because the Office of Foods was not established until August 7, 2009, and the Center for Tobacco Products was not established until August 19, 2009, we did not include them in our review.

⁵Respondents had the option of reading these questions on their use of performance information and changing their answer to the previous question.

⁶GAO, *Food and Drug Administration: 2009 FDA Managers Survey on Performance and Management Issues, an E-supplement to GAO-10-279*, [GAO-10-280SP](#) (Washington, D.C.: February 2010).

In addition to sampling errors, the practical difficulties of conducting any survey may also introduce other types of errors, commonly referred to as nonsampling errors. For example, difficulties in how a particular question is interpreted, in the sources of information that are available to respondents, or in how the data were entered into a database or were analyzed can introduce unwanted variability into the survey results. With this survey, we took a number of steps to minimize these nonsampling errors. For example, GAO staff with subject matter expertise designed the questionnaires in collaboration with GAO survey specialists. Draft questionnaires were pretested with FDA managers to ensure that the questions were relevant and clearly stated. When the data were analyzed, a second, independent GAO analyst independently verified all analyses. This verification included a line by line review of all analysis programs and results to ensure the accuracy of the code and the appropriateness of the methods used for the computer generated analysis. Since this was a Web-based survey, respondents entered their answers directly into the electronic questionnaire, thereby eliminating the need to have the data keyed into a database and avoiding data entry errors.

To identify FDA's management challenges, we reviewed evaluations of FDA since January 2007 from the following sources: 2007 and 2009 reports from GAO's high-risk series;⁷ the Institute of Medicine's 2008 report, *HHS in the 21st Century: Charting a New Course for a Healthier America*;⁸ the Department of Health and Human Services (HHS) fiscal years 2007 and 2008 financial reports,⁹ which include the Inspector General's yearly summary of management and performance challenges; and the FDA Science Board's 2007 report, *FDA Science and Mission at Risk*.¹⁰ To determine whether FDA's 2007 Strategic Action Plan contains strategies to

⁷GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: January 2009); and *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007).

⁸Leonard D. Schaeffer, Andrea M. Schultz, and Judith A. Salerno, Editors, Institute of Medicine of the National Academies, Committee on Improving the Organization of the U.S. Department of Health and Human Services (HHS) to Advance the Health of Our Population, *HHS in the 21st Century: Charting a New Course for a Healthier America* (Washington, D.C.: 2009).

⁹Department of Health and Human Services, *Fiscal Year 2007 Agency Financial Report* (November 2007), <http://www.hhs.gov/afr/> (accessed Dec. 11, 2008); and *Fiscal Year 2008 Agency Financial Report* (November 2008), <http://www.hhs.gov/afr/> (accessed Dec. 11, 2008).

¹⁰FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Rockville, Md.: November 2007).

address identified challenges, we compared the challenges we identified with our analysis of the plan. We verified both our work identifying challenges and our work reviewing whether FDA's Strategic Action Plan addressed those challenges with FDA officials. To examine the progress that FDA has reported toward meeting identified challenges, we reviewed documentation FDA provided to us in which it reported its efforts to address management challenges GAO identified since releasing its Strategic Action Plan in 2007. We also reviewed documentation from FDA on its fiscal years 2008 and 2009 hiring initiative, and its 2009 succession plan, among others. Last, we interviewed FDA officials on their efforts to address challenges. To determine FDA's progress in meeting those management challenges, we reviewed our 2009 survey for respondents' views of FDA's progress on its management challenges. We also reviewed the survey for FDA managers' detailed written responses on the top issues FDA's management should address to achieve agency goals and responsibilities. To do this, two GAO analysts independently reviewed and categorized each response, then reconciled any differences in their independent categorizations. We reported on examples that were illustrative of the responses in any given category. In addition, we reviewed the OPM Human Capital Assessment and Accountability Framework (HCAAF), which provides guidance on human capital planning and management;¹¹ a prior GAO report on FDA's information technology;¹² and the FDA Science Board's assessment of FDA's information technology and management.¹³

To determine the extent to which FDA's annual performance measures are results-oriented, we reviewed prior GAO work that identified leading practices agencies could follow to develop results-oriented performance measures.¹⁴ These included all seven practices noted in our February 1999

¹¹Office of Personnel Management, *HCAAF Practitioners' Guide* (Washington, D.C.: September 2005).

¹²GAO, *Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernization Efforts*, [GAO-09-523](#) (Washington, D.C.: June 2, 2009).

¹³FDA Science Board, *Subcommittee Review of Information Technology* (Washington, D.C.: August 2009).

¹⁴GAO, *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decisionmakers*, [GAO/GGD/AIMD-99-69](#) (Washington, D.C.: Feb. 26, 1999); and *Agencies' Annual Performance Plans Under the Results Act: An Assessment Guide to Facilitate Congressional Decisionmaking*, [GAO/GGD/AIMD-10.1.18](#) (Washington, D.C.: February 1998).

report on articulating a results orientation as well as one practice from our February 1998 report, which noted that to focus on results, agencies should include outcome measures in performance plans whenever possible. We chose these practices because we determined that they had relevance to creating results-oriented performance measures. From these eight practices, we identified eight characteristics of results-oriented performance measures and compared these characteristics with the 48 annual performance measures included in the President's fiscal year 2010 budget request for FDA. These performance measures are linked to and organized by FDA's main centers and offices. As part of this comparison, we examined FDA's and HHS's strategic goals. Finally, we interviewed FDA officials to obtain their views on the use of results-oriented performance measures.

To determine the extent to which FDA has aligned its activities and resources to its strategic goals, we reviewed leading practices on effective strategic alignment from prior GAO work and guidance from the Office of Management and Budget.¹⁵ We determined the extent to which FDA was consistent with these leading practices by comparing FDA's strategic goals from its 2007 Strategic Action Plan with documentation on the agency's activities and resources. Specifically, we examined portions of the budget requests for FDA in fiscal year 2010, including FDA's Narratives by Activity, Summary of Full Cost table, and Functional Activities Tables. We also examined FDA's planning documents, such as the 2007 *Food Protection Plan*,¹⁶ the National Center for Toxicological Research's 2009-2013 strategic plan, and CDRH's fiscal year 2008-2010 operational plan, among others. In addition, we reviewed a selection of performance plans covering individual FDA employees from Senior Executive Service to career service. We also interviewed FDA officials on their efforts to align activities and resources to goals.

To review FDA managers' use of performance information in decision making, we reviewed prior GAO work on enhancing agency use of performance information for management decision making, which

¹⁵GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, [GAO/GGD-96-118](#) (Washington, D.C.: June 1996); [GAO-04-38](#); and Office of Management and Budget, Executive Office of the President, OMB Cir. No. A-11, Preparation, Submission, and Execution of the Budget, Sec. 220, p. 1 (2009).

¹⁶Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan* (Washington, D.C.: 2007).

identified four broad types of management decisions for which federal managers can use performance information and five different types of practices that can contribute to greater use of performance information. To review FDA managers' use of performance information related to these four types of management decisions, we analyzed responses to seven questions in our 2009 survey measuring managers' reported use of performance information to make different management decisions. We identified the percentage of managers reporting that they used performance information to a "great" or a "very great" extent on those questions, and we compared those results with results from our 2007 survey of federal managers. To review FDA managers' reported application of practices to encourage the use of performance information, we analyzed responses to four other questions in our 2009 survey that measured managers' reported use of those practices, again comparing the portion of "great" and "very great" responses with the results of our 2007 survey of federal managers. We did not use the survey to review one of the five previously identified practices—aligning agencywide goals, objectives, and measures—because we addressed this issue in our third research objective using other research methods. In addition, we examined responses to our survey question asking FDA managers whether they had received training in six different areas related to the use of performance information, comparing responses with comparable results from our 2007 survey.

We conducted our work from December 2008 to February 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Crosswalk of FDA's Strategic Goals and Objectives to Fiscal Year 2010 Performance Measures

FDA strategic goals and objectives	Number of related fiscal year 2010 performance measures
Strategic Goal 1: Strengthen FDA for Today and Tomorrow	
Objective 1.1: Strengthen the scientific foundation of FDA's regulatory mission	0
Objective 1.2: Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensures integrity and accountability in regulatory decision making	0
Objective 1.3: Enhance partnerships and communications	0
Objective 1.4: Strengthen FDA's base of operations	2
Strategic Goal 2: Improve Patient and Consumer Safety	
Objective 2.1: Strengthen the science that supports product safety	0
Objective 2.2: Improve information systems for problem detection and public communication about product safety	3
Objective 2.3: Provide patients and consumers with better access to clear and timely risk-benefit information for medical products	0
Objective 2.4: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition	1
Strategic Goal 3: Increase Access to New Medical and Food Products	
Objective 3.1: Increase the number of safe and effective new medical products available to patients	9
Objective 3.2: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science	11
Objective 3.3: Increase access to safe and nutritious new food products	1
Strategic Goal 4: Improve the Quality and Safety of Manufactured Products and the Supply Chain	
Objective 4.1: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution	5
Objective 4.2: Detect safety problems earlier and better target interventions to prevent harm to consumers	15
Objective 4.3: Respond more quickly and effectively to emerging safety problems, through better information, better coordination, and better communication	1

Source: GAO analysis of FDA data.

Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JAN 22 2010

Lisa Shames, Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Shames:

Enclosed are the Departments comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "Food and Drug Administration: Opportunities Exist to Better Address Management Challenges (GAO-10-279).

The Department appreciates the opportunity to comment on this report before its publication.

Sincerely,


Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: OPPORTUNITIES EXIST TO BETTER ADDRESS MANAGEMENT CHALLENGES" (GAO-10-279)

The Department appreciates the opportunity to review and comment on the U.S. Government Accountability Office (GAO) draft report.

Given the timing of GAO's study, and its focus on documentation of past strategies and management practices, the draft report represents a baseline against which the FDA leadership can measure its ongoing progress.

FDA agrees with GAO's Recommendations for Executive Action. Many of these recommendations are well on their way to full implementation.

FDA Progress in Addressing Human Capital Planning

GAO recommends that the Commissioner of Food and Drugs develop a strategic human capital plan and issue an updated workforce plan.

FDA agrees with this recommendation. In fact, considerable progress has been made in human resource planning. The agency successfully conducted a hiring surge of over 2,500 staff in 2008 – 2009, through coordinated workforce planning that included:

- systematic identification of staffing needs, including specific occupational needs by Center/Office, grade levels, and locations;
- criteria for utilizing appropriate hiring authorities (e.g., Title 5, Commissioned Corps, etc.);
- coordinated approaches to offering monetary and non-monetary recruitment incentives; and
- a request to the Office of Personnel Management for Direct Hire authority for many of the mission critical occupations.

This well-planned and well-executed hiring surge met or exceeded all of FDA's hiring targets for 2009, and demonstrated FDA's ability to recruit and hire skilled mission-critical staff across the agency.

FDA is currently engaged in the process of developing a strategic human capital plan. In September, 2009, FDA awarded a contract to support development of a human capital plan and updated workforce plan. Program-level human resources (HR) planning is continuing in support of the agency-wide plans and as a routine part of annual operating plan development. In addition, FDA is working with HHS to review the Rockville HR Center's progress.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: OPPORTUNITIES EXIST TO BETTER ADDRESS MANAGEMENT CHALLENGES" (GAO-10-279)

FDA's Progress in Developing Results-Oriented Performance Measures

GAO recommends that the Commissioner of Food and Drugs work to make the agency's performance measures more results oriented.

FDA agrees with this recommendation, and is working to improve and expand the performance measures to be included in the FY 2011 President's Budget. In fact, FDA has improved the agency's performance measures over the past year.

For example, FDA has continued to refine its performance measures that support the Prescription Drug User Fee Act (PDUFA), Medical Device User Fee and Modernization Act (MDUFMA), Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA), as part of the periodic reauthorization of these programs. These user fee programs incorporate a broad array of performance goals for the agency's human drugs, biologics, medical devices, and animal drug programs. FDA reports detailed information about program goals, activities, and performance to Congress annually.

FDA also tracks several outcome measures. For example, FDA has established several food safety performance goals that align with public health outcome measures in the Healthy People 2010 program, specifically regarding measures and targets for reducing the incidence of infection with several common foodborne pathogens. FDA also tracks an intermediate outcome goal to increase the number of state, local and tribal regulatory agencies in the U.S. that are enrolled in the Voluntary National Retail Food Regulatory Program, and which meet two or more of the standards. FDA worked collaboratively with the Centers for Disease Control and the U.S. Department of Agriculture's Food Safety Inspection Service to develop results-oriented measures in support of the White House Food Safety Working Group, and developed a high-priority performance goal regarding reduction of *Salmonella Enteritidis* infections as part of an initiative led by the Office of Management and Budget.

FDA also has been developing logic models that link inputs, activities, and outputs to intermediate and public health outcomes that align with the agency's strategic objectives; drafting and refining long-term outcome measures that align with the logic models and strategic objectives; and developing a new comprehensive performance tracking and management system, which FDA is implementing in FY 2010. This new performance management approach will expand the range of FDA's performance measures and establish regular review meetings with senior executives to support the use of performance information in management decision making.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: OPPORTUNITIES EXIST TO BETTER ADDRESS MANAGEMENT CHALLENGES" (GAO-10-279)

Alignment of Program Activities with Agency Goals

GAO recommends that the Commissioner of Food and Drugs direct each of the agency's Centers and Offices to clearly align their program activities to FDA's strategic goals in documents such as the budget request or Center and Office-level documents.

FDA agrees that Center and Office program activities should be aligned to FDA's strategic goals and objectives.

In fact, this alignment is well established at the agency. All eight Centers and Offices link their activities to FDA strategic goals and objectives, not only through their planning activities but also through staff performance management plans. All eight Centers and Offices align their annual performance measures to FDA's strategic objectives.

GAO notes that in FDA's FY 2009 and FY 2010 performance budget submissions, only four Centers and Offices clearly documented the alignment of their activities to FDA strategic goals. FDA is making its overall alignment evident for all eight Centers in the FY 2011 performance budget submission by including a new table that links each subprogram area to FDA's strategic objectives.

Linking Workload to Strategic Goals

GAO recommends that the Commissioner of Food and Drugs direct the agency's Centers and Offices to track their workload by strategic goal.

FDA agrees that such workload tracking is an important goal. The FDA's National Center for Toxicologic Research (NCTR) and Center for Veterinary Medicine (CVM) already have the ability to link employee workload to agency goals. The other Centers and ORA have, to varying degrees, partial time reporting systems and performance tracking systems that, when viewed as a whole, provide managers with regular information about how their employees' work relates to FDA goals. These systems provide relevant and actionable management information consistent with generally accepted accounting principles. FDA also notes that its user fee reports to Congress provide solid evidence that FDA managers are using workload information to achieve key performance objectives.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: OPPORTUNITIES EXIST TO BETTER ADDRESS MANAGEMENT CHALLENGES" (GAO-10-279)

FDA is laying the groundwork for further improvement. In December 2009, FDA awarded a contract to support the development of a comprehensive methodology and set of tools for estimating the resources needed to address FDA's mission responsibilities. The workload models produced by this project will serve as a foundation for further development of workload tracking methods that can be linked to agency goals.

Expanding Performance Training for Managers

GAO recommends that the Commissioner of Food and Drugs work to build its capacity to collect and analyze performance information by expanding training for managers on topics related to performance information.

FDA agrees with GAO's recommendation. In fact, FDA is currently developing a training plan and Statement of Work for helping managers and staff analysts understand the performance budget process, develop performance measures, and use performance information in management decision making. FDA is planning to develop or purchase the training modules and pilot them in FY 2010, and make the training available in FY 2011.

Additional Comment: GAO's Comparison of 2009 and 2007 Survey Results Regarding Training Is Invalid

FDA appreciates GAO's efforts to conduct a survey of FDA managers, and FDA will continue to analyze the results as it plans and implements improvements to its programs. However, FDA has concerns about the way GAO reported the results in the draft report.

In the draft report, GAO compares the results of the 2009 survey of FDA managers to the results of a 2007 GAO survey of managers across all federal agencies. The results for Question 17 in the 2009 survey asks FDA managers if they have received six types of training related to performance information. GAO compares this result to the finding from 2007 for all federal managers.

This comparison is invalid. The response options (or "scale") in the two surveys are different. FDA managers were given 3 response options ("Yes," "No," or "Not sure"), whereas the other federal managers were given only 2 response options ("Yes" and "No"). The proportion of FDA respondents that answered "Not sure" is substantial, ranging from 11% to 19% across the 6 questions. Because the response options were different, a direct comparison is inappropriate.

Appendix IV: GAO Contacts and Staff Acknowledgments

GAO Contacts

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Staff Acknowledgments

In addition to the contacts named above, Sheila K. Avruch, Assistant Director, and J. Alfredo Gómez, Assistant Director; James D. Ashley; Thomas M. Beall; Kevin S. Bray; Deirdre G. Brown; Candace M. Carpenter; Shaunessye D. Curry; Krister P. Friday; Catherine M. Hurley; Stuart M. Kaufman; Martha Kelly; Julian P. Klazkin; Valerie C. Melvin; Karine E. McClosky; Mark R. Needham; Katherine M. Raheb; Vasiliki Theodoropoulos, Stephen C. Ulrich; and Russell Voth made key contributions to this report.

Related GAO Products

FDA—High-Risk Issues

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