



THE STATE OF THE FDA WORKFORCE

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PARTNERSHIP FOR PUBLIC SERVICE

The Partnership for Public Service is a nonpartisan, nonprofit organization that works to revitalize the federal government by inspiring a new generation to serve and by transforming the way government works.

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INTRODUCTION AND SUMMARY

The Food and Drug Administration's (FDA)

mission is to protect the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, tobacco products and products that emit radiation. All told, FDA-regulated industries account for approximately \$1 trillion in annual spending in the United States, or 25 cents of every consumer dollar.

In 2007, an authoritative and troubling report by the FDA Science Board subcommittee on science and technology found that escalating demands combined with inadequate funding had significantly impeded the agency's ability to keep pace with advances in science, the complexity of new products and the globalization of the industries that it regulates.

In particular, the report, FDA Science and Mission at Risk, said "the scientific workforce does not have sufficient capacity and capability" and is "not positioned to meet current or emerging regulatory responsibilities." The report found that the funding shortfalls and intense work pressures caused top FDA scientists to leave, created problems carrying out fundamental research, hurt recruitment of both young and mature scientific talent, and left the agency with significant gaps in scientific expertise.

The Partnership for Public Service was asked by the Pew Charitable Trusts to determine if the FDA has made progress in shoring up its scientific and technical workforce since the Science Board sounded the alarm. As part of our review, we examined whether the FDA had adopted any of the report's workforce recommendations or taken other steps to correct the problems; how FDA employees and leadership view the current state of the workforce; and what the agency should do in the future to improve its recruitment, hiring and retention practices.

From our review, we discovered that the FDA has made progress since the Science Board issued its findings, including taking steps to expand its workforce. But we also found that the FDA continues to have significant workforce and management challenges in the scientific and medical arenas that need to be addressed for the agency to fulfill its public health obligations to the American public and its responsibilities to the industries it regulates.

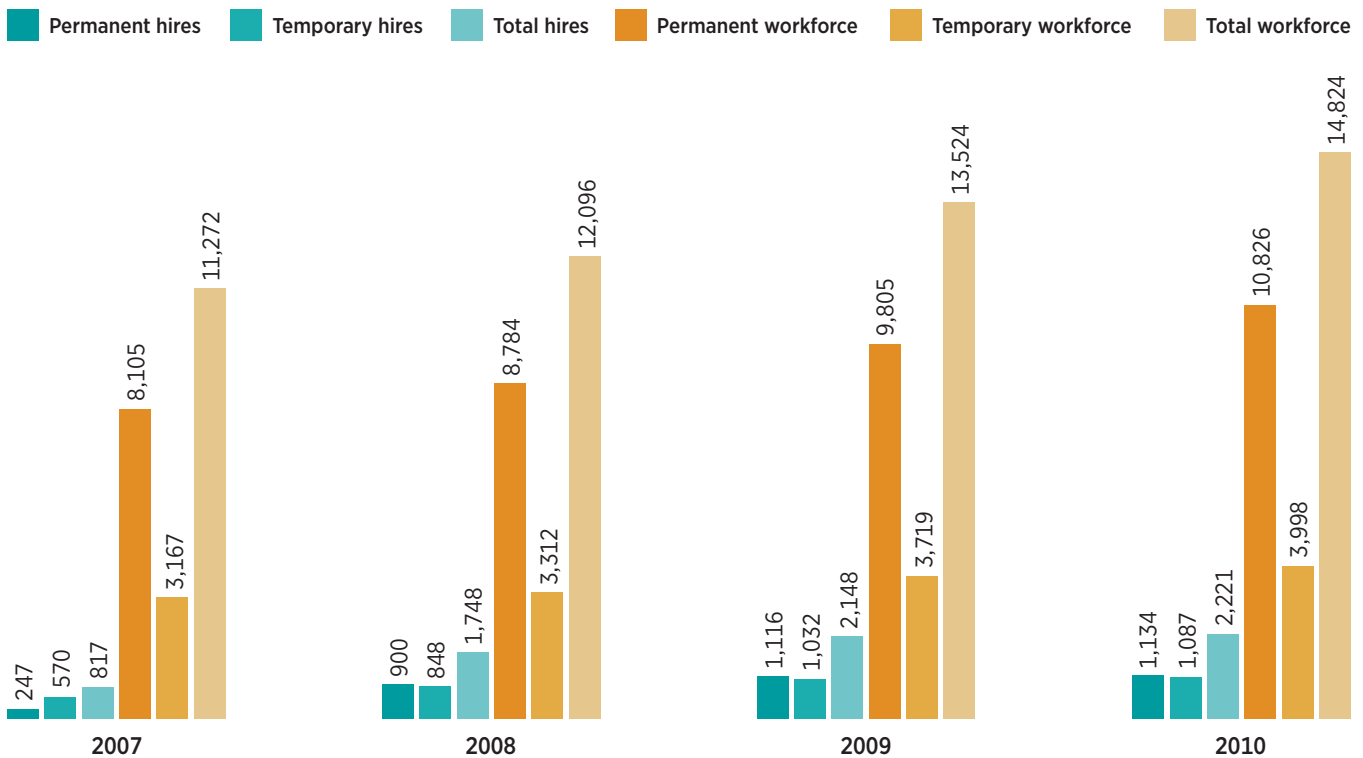
Given the broad scope of this effort, we focused our inquiry on the following FDA offices and centers, which compose 74 percent of the agency's entire workforce: the Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Drug Evaluation and Research (CDER); Office of the Chief Scientist; and Office of Regulatory Affairs (ORA).

The centers and offices have different histories, cultures and leadership, and do not always operate the same way when it comes to human capital management. However, they face similar challenges regarding workforce recruitment, development and retention. We found that some centers have developed commendable human resources (HR) management policies and practices. We also found, however, that more could be done to share these practices and resources across centers and across management teams.

Between November 2011 and January 2012, we engaged in an extensive literature review, analyzed government data from a variety of sources, reviewed the FDA Strategic Human Capital Plan, conducted more than two dozen interviews with a cross-section of FDA managers and directors, and had conversations with pharmaceutical industry professionals and those in academia who help science, technology, engineering, mathematics and

FDA's growing permanent and temporary workforce by fiscal year

The workforce has grown steadily in the past four years.



Source: Data from FedScope, the Office of Personnel Management's Planning and Policy Data analysis office. Chart contains workforce size for all of FDA including all centers. For full data definitions and sources, see Chapter Two.

medicine (STEMM) graduates find jobs. FDA and Department of Health and Human Services (HHS) human resource directors as well as FDA senior leadership provided us with full cooperation, sharing information and openly discussing the management and human capital challenges that they are facing.

Steps taken to meet workforce needs since 2007

The FDA's need for adequate funding to meet its ever-increasing responsibilities was ignored for many years. The 2007 report raised the political stakes and laid out the urgency for new appropriations. Other factors, including highly publicized lapses in FDA oversight of drugs,

food and medical devices, also drew attention and provided an impetus for change.

Congress responded by increasing the FDA's annual appropriation. In fiscal 2007, the FDA received the funding of \$1.5 billion. By fiscal 2012, this grew to \$2.5 billion, nearly a 60 percent increase over five fiscal years. This additional funding has increased the agency's capacity, as it is mandated for specific purposes centered on expanding the workforce and speeding up the product review processes.

The FDA is also receiving substantial funding through industry user fees, which grew from about \$597 million in fiscal 2009 to \$1.3 billion in 2012. The fiscal 2013 bud-

get projects industry user fees totaling about \$2 billion, or roughly 44 percent of the total amount of money available to the agency.

The extra funding enabled the FDA to expand its workforce from 11,272 employees in fiscal 2007 to 14,824 in fiscal 2010, a rise of 31.5 percent. Those hired included consumer safety officers, chemists, microbiologists and medical officers who were dispersed across all FDA centers and offices. A sizable number of the new employees were hired on a temporary, short-term basis. The hiring surge gave the FDA a needed infusion of manpower but created a whole new set of human resource and leadership challenges that included ensuring that new talent was

properly acclimated and managed effectively. At the same time that the agency was building up its workforce and dealing with added management issues, Congress gave the FDA new responsibilities, including the regulation of tobacco and mandates to increase its inspections of foreign food and drug facilities and to take added steps to prevent food-borne illnesses.

Responding to other Science Board recommendations, the FDA established cross-agency working groups to address knowledge gaps, discuss priority scientific issues and plan for staff training and workshops. The agency brought in visiting scientists to give seminars and lectures, expanded external collaboration through 20 academic partnerships and collaborated with external organizations to conduct conferences, seminars or educational programs.

The FDA also established an exchange program for scientists from academia and other federal organizations to come to the FDA for short-term assignments. It set up the Commissioner's Fellowship Program for 50 individuals a year that combines coursework with a regulatory science research project, began a new training program for medical device reviewers, and administered a peer review program that since 2008 has resulted in a yearly average of 132 non-supervisory promotions of scientists to higher grade levels.

In addition, the agency developed a comprehensive Strategic Human Capital Plan 2010–2012 that provided an analysis of several human capital challenges and problems that hinder its ability to accomplish its goals, and a corresponding 2010 Workforce Analysis and 2011–2012 Workforce Plan that offer a detailed analysis of loss/attrition, hiring and training, competency gaps and leadership positions.

FDA officials reported to us in interviews that the plan and the associated workforce planning ex-

ercise have served as a roadmap for actions that need to be taken to address many of the agency's workforce challenges. FDA also said that many of its centers and offices have human capital initiatives underway in support of workforce improvement efforts.

Finally, the FDA said that it is using the Office of Personnel Management's (OPM) five-tier performance system that encourages agencies to make greater distinctions among their executives in terms of their performance and results achieved. FDA officials told us that in its implementation of this system, leadership will be a key performance element in executive performance plans, with a particular emphasis on leading and developing the workforce. This seemingly modest change in process could be quite valuable.

More needs to be done

While the FDA has taken a number of positive steps to address its workforce challenges, our interviews with FDA officials identified areas where the agency continues to struggle to make progress. One basic problem is that, despite some improvements, the FDA's hiring process still takes far too long to bring new talent onboard and too often does not deliver quality candidates.

FDA officials said their effort to recruit and hire top talent had been impeded by the poor quality of the human resources services provided by a centralized HR staff at FDA's parent agency, the Department of Health and Human Services (HHS).

In February 2012, HHS Secretary Kathleen Sebelius made the decision to return the HR function from headquarters to the FDA. The FDA Office of Human Resources (OHR) organization became operational in July 2012. The new OHR organizational structure holds the promise of helping better recruit scientific talent to meet the needs of the agency

and improve career training and leadership development.

FDA officials said they are determined to rebuild the agency's human resources capabilities.

"To assure the organization is able to effectively deliver services to FDA customers, we have appropriately staffed the new organization with adequate resources, including a Senior Executive Service (SES) director, a deputy for operations, and another deputy to lead human capital initiatives," an FDA official said. "This will allow a dedicated focus on targeted efforts to rebuild human capital, improve the HR operations and implement innovative programs and systems that modernize the FDA's approach to managing its workforce."

How this is carried out and the degree to which FDA supervisors and managers are involved will be major determinants in the agency's efforts to meet its goals.

One area of focus for the new FDA HR operation should be on developing long-term relationships with academic institutions, the private sector and other talent sources to build pipelines for the type of scientific skills it needs today and that it will need in the future. Our review found the agency has not been proactive in this regard.

In addition, we found the agency is not doing enough to train new employees, familiarize them with their assignments and foster their professional development. There also is no systematic plan to recruit executive talent from outside the agency to bring fresh perspectives to the job, nor a dedicated effort to broaden the managerial experience of current executives by giving them rotating assignments within the FDA or in other agencies.

Our analysis of the Partnership's 2011 *Best Places to Work in the Federal Government*[®] data and our interviews also discovered that many FDA employees have worries about

whether there will be opportunities to advance in their careers. The *Best Places to Work* data included a number of other red flags regarding talent management issues. These involved employee concerns with the recognition they receive for doing a good job and the information they receive from managers about what is going on in the organization. The data also showed that nearly half of those surveyed were dissatisfied with senior leadership and had concerns about fairness in the workplace.

In addition, the Partnership's review of the promising Human Capital Plan and the workforce planning documents showed that many of the dates established for various improvement activities either had passed or were soon to pass. Further, it was unclear how many of the actions were taken within the self-imposed timeframes established in the plan.

With the formation of the new OHR organization, this is an excellent time to assess the progress, update the plan and revisit the FDA's overall human capital strategy. The FDA reports that it is in the process of doing both in the context of the significant HR reorganization. Careful follow-through in this regard will be important. It will be critical that this update and re-examination not be considered simply an OHR responsibility. FDA managers and executives must be involved and must work closely with the OHR staff and leadership to determine if it is meeting its hiring needs.

Recommendations

Based on our findings, there are a number of recommendations we believe will help the FDA improve its mission-critical scientific staffing needs. Our full recommendations are detailed at the end of this report, but our topline proposals include the following:

- **Hiring and recruiting:** The FDA needs to develop targeted recruitment programs and talent pipelines for high-priority scientific and medical disciplines, speed up the hiring process, recruit executives from outside the FDA to bring fresh perspectives to the organization, and ensure that subject matter experts, not just HR staff, are meaningfully involved in the assessment of job applicants for critical STEM leadership and project management positions.
- **Update workforce and human capital plans:** The agency must follow through on plans to update the FDA Strategic Human Capital Plan and Workforce Analysis Plan agency-wide and for each FDA center, involve key FDA managers and executives in the development of these plans, and make sure they “own” those workforce plans and are held accountable for meeting goals and objectives.
- **Measure and track progress:** Include HR managers and those involved in restructuring the HR system in the gathering and updating of information that will help assess progress in meeting the agency's scientific hiring needs. This should include data that identifies competency gaps, progress made in closing those gaps and tracking the success of strategies for meeting talent needs.
- **Continue to invest in career training and leadership development:** Create better defined career paths for STEM employees to help them understand what they need to do to move up to the next level, develop a more robust strategy for leadership development within the FDA scientific community and support professional growth through training.
- **Don't neglect retention and succession planning:** Develop replacement strategies, using temporary or term appointments, to ensure that a healthy pipeline of mission-critical talent is available when needed, and take steps to address job categories that have high rates of attrition, including pharmacists and consumer safety officers.

FDA'S STRENGTHS AND CHALLENGES

The FDA has a highly educated, motivated and dedicated workforce that understands the importance of the agency's mission in protecting the public health and fully embraces the challenges and responsibilities that come with regulating drugs, medical devices and a host of other products.

At the same time, we found in interviews with individuals inside and outside the FDA, as well as in a review of FDA documents and independent reports, that the agency has many deficiencies when it comes to managing its workforce. These include problems recruiting, hiring, developing and retaining scientific talent, coordinating management activities internally, keeping up with scientific advances and handling an ever-increasing workload.

The management and staff of the FDA are well aware of these issues, some of which were raised in the 2007 Mission at Risk report. We also found that the FDA is still grappling with many of these critical workforce challenges, from a broken hiring system to employee and leadership development and workload issues. And, even as the FDA staff and budgets have grown, the demands on the agency and its workforce have increased alongside new responsibilities required by Congress regarding the import of foreign foods and the regulation of tobacco products.

FDA'S STRENGTHS

FDA employees care about what they do and the mission of the agency

There is near consensus among current FDA employees, industry professionals and academia that the scientists who work at the FDA are committed individuals who are passionate about the mission of protecting public health and find rewards from the impact of their daily work. They believe their jobs are important. This is true as well for the FDA's leadership.

This commitment is reflected in the *Best Places to Work* data, with FDA employees giving their organization top scores when it comes to their satisfaction with how their skills align with the agency's mission.

Top scientific talent who work at FDA want to be involved in cutting-edge science

STEMM employees seek out challenges and pioneering advancements in their fields. They are highly motivated and want to work side-by-side with the best and the brightest. They find their work personally interesting and invigorating and are creative individuals. To quote one former Center director, "Scientists like to see new drugs and reviewers like to see state-of-the-art science. It's a thrill, gives them panache."

FDA has perpetual needs for top scientific talent

There is great demand for top STEM talent throughout our country, but nowhere is it more important than in the federal government and at the FDA. The FDA's mission and the critical occupational skills it needs to perform effectively are not going away, so it is essential that the FDA has the ability to build and maintain a strong workforce that will lead the way into the future of science.

Direct hire authority and Title 42

Direct hire authority enables an agency to hire any qualified applicant without requiring candidates to go through the full standard federal application process, while a Title 42 provision allows the FDA to appoint highly qualified consultants, scientists and engineers at a pay scale outside civil service laws. Both provisions allow the FDA to be more competitive in acquiring top scientific talent by speeding up the recruitment process.

FDA'S CHALLENGES

TALENT ACQUISITION

Hiring process is broken and needs fixing

There was a broad consensus that the hiring process remains slow and cumbersome. One top FDA official told us that the agency often loses out on good candidates because "government has a timeline that isn't reasonable for people in the real world."

Officially, the FDA reports that it has made "significant progress" on hiring by reducing the time to bring a candidate on board from approximately 159 days to less than 80 days. "It is clear to departmental (HHS) leadership, based on our conversations, that we still have more work to do in this area," said one FDA of-

ficial. The time to hire, of course, is an average, meaning that for some jobs, particularly those hired from outside government, the timeline is often much longer. In our interviews, we heard over and over that it takes an average of about six months, not 80 days, to circulate a formal announcement and get a new employee on board. Many FDA officials shared the experience of losing out on top talent because of the long human resources turnaround time.

While the government may never have the hiring flexibility of private corporations, this lag time is pronounced within a human resources system that was centralized within HHS beginning in 2004, when 40 separate HR offices for departmental agencies were combined into just four. After the consolidation, FDA officials said there was an increased lack of communication and a disconnect between the HR managers trying to fill positions for the FDA and the key program managers who knew what type of skills they needed to fit the position. They said the job descriptions became generic and the responsibilities and requirements were not described in easily digestible ways. These standard position descriptions were originally seen as a way to speed up the hiring process, but many of the FDA officials interviewed said they failed both candidates and FDA managers. One position description does not fit all positions; a biologist who works on vaccines is not the same as a biologist who works with plants.

Many of those we interviewed said the centralization was designed to help promote a "One Department" philosophy, but it made recruitment and hiring much worse. In the words of one former director, this has been a "total fiasco." In addition, the USA-JOBS website, although recently revamped in an effort to make it more user-friendly, was universally described as "cumbersome," "not intuitive" and "a black hole" for FDA jobs.

On Jan. 20, 2012, FDA Commissioner Margaret Hamburg announced that the HR functions formerly residing in HHS would return to the FDA, a process that was officially launched in July 2012 and will take time to implement. This change could make a big difference in the agency's ability to get the people it needs and do so more quickly.

Lack of talent pipelines

One recurring theme among those who hire in the scientific and regulatory fields at the FDA is their inability to be proactive in developing relationships with universities and the private sector to recruit scientific talent. As one interviewee said, "you have to go above and beyond" to find the right people as opposed to just creating a vacancy announcement. While intern and fellowship programs are important, they lack uniformity at the FDA. There are center-specific internships and fellowships, but they are sporadic, having been cut back considerably in recent years. In response to the Mission at Risk report, the agency in 2008 established the Commissioner's Fellowship Program. The two-year program combines coursework with the completion of a regulatory science research project and selects up to 50 fellows each year. The FDA reported that 74 percent of the fellows who graduated in 2010 and 2011 remained at the agency as of early 2012.

FDA branding/image issues

According to many FDA program managers, as well as academics involved in helping students with STEM majors find employment, there is a lack of understanding among these students about what the FDA does and the talent it needs. There is no systematic communications program in place to provide public visibility about the types of careers available and the interesting science work being done at the

agency. FDA's website could be vastly improved to better showcase the opportunities for science and technology majors and the rewarding jobs available within the FDA.

As a regulatory body, the FDA often experiences negative reviews from private industry and from Congress. These negative image issues add to the challenges of bringing highly qualified scientists into the workforce. One biologist said it took her seven years to get over the "FDA stigma" and actually make the leap to come work at the agency. Even though the work at the FDA was more in line with her field and what she wanted to pursue, she refused job offers after hearing negative comments about the FDA and having a the feeling that the FDA was not the place for top scientists. This sentiment was echoed by many reviewers and scientists who work at the FDA. Top STEM talent have options, and for some, the FDA is seen as an option only if people can't get work in academia, industry or at the National Institutes of Health (NIH). The FDA is seen as a safe landing for some, not the place to go if you want to be innovative. The FDA, like other agencies, also faces tough challenges in its general recruiting and hiring because of perceptions of the government. Trust in the federal government has reached an abysmal low.¹

At CDRH, for example, there has been a constant drumbeat from industry regarding the pre-market review and approval programs, with complaints that they aren't predictable, consistent, transparent or time-

ly. The FDA routinely has come under the congressional spotlight and been criticized for either being too lax or too stringent with the industries it regulates. While the political dynamic will always be part of the process and difficult for the FDA to control, its impact can hurt morale and create an image that may discourage prospective employees.

MANAGING, RETAINING AND DEVELOPING TALENT

Lack of meaningful onboarding program for new employees

We learned through interviews that most of the onboarding for new employees entails a high-level introduction to the agency. There are center-specific orientations held once per quarter, but they are not directed at specific jobs. The process tends to vary greatly from field office to field office and center to center.

Onboarding at the FDA does not always engage new employees in a productive way. There is an extensive paperwork component for new employees designed to ensure that the scientific staff members are free of conflicts of interest, but there are not enough mentors to encourage employee engagement and help newly hired workers get a feel for the culture. According to several interviewees, there also is a lack of simple technical support once new employees arrive to obtain such basic necessities as a computer and a telephone.

While some offices indicate they have "buddy-system" programs in place, not all do, and it can be taxing on often overworked employees to be in charge of bringing their colleagues up to speed. Many STEM employees say they are given work and learning assignments to start on right away even though they often have not been given the proper equipment or explanations they need to do their jobs.

From interviews with HR managers, program managers and employees, it is clear that some offices within the FDA do a better job of bringing in and grooming new employees than others. Part of this inconsistency is due to the diverse types of jobs within the FDA as, well as the fact that it is a multilocation organization. The ORA alone spans 20 district offices and 13 laboratories. There are pockets of best practices regarding onboarding at the FDA, but there is little accountability. Like recruitment issues, the disjointed nature of HR at the FDA hurts its overall onboarding performance.

Workload/lack of agency advancement

The interesting nature of the FDA's work is a major draw, but an ever-increasing workload makes it difficult to retain many mission-critical employees and to meet agency goals. Even with the increased hiring, there are shortfalls in some areas. As an agency official from one of our targeted centers said, "If you can get me FTEs, I'll take care of the rest." The official noted as an example that 2.7 million people are affected by food allergens, but his office, which has jurisdiction over this issue, has just four people working in this area.

Among many former FDA scientists, the lack of advancement opportunity is also cited as another major workplace criticism and a main reason for leaving the agency. Scientists often are seen as "lab people," not leaders, and once employees reach a certain level, there are few chances to advance within the agency. FDA STEM employees tend to have fewer advancement opportunities and must make lateral moves across the organization to gain knowledge and broaden their expertise. The *Best Places to Work* data found concern among employees regarding career advancement, the recognition they receive for doing a good job, the lack of information they re-

¹ According to the 2010 Pew Research Center survey on public attitudes toward government, Distrust, Discontent and Partisan Rancor, April 18, 2010, the proportion of the American public saying they can trust the government to do the right thing had fallen to 22 percent, one of its lowest levels in more than 50 years. Three percent said they could trust government "just about always," and 19 percent said they could trust government "most of the time."

ceive from management on what is going on within their organization, and how well their talents are used in the workplace.

Heavy reliance on temporary workforce

More than one-fourth of FDA's employees are not in permanent, full-time jobs, but rather hold temporary positions for two to four years. The practice of hiring temporary employees has a number of benefits as well as costs to the agency. On the plus side, temporary employees can be hired more quickly than permanent workers, and they can infuse the agency with fresh perspectives and needed scientific skills and expertise that may be lacking, particularly in many of the emerging scientific fields. The practice also gives the FDA some flexibility in growing or reducing staffing when appropriate, but it has a downside as well. Wide use of temporary employees leads to anticipated but disruptive turnover, lack of continuity and potential difficulty in meeting workload demands if jobs remain vacant for long periods. The system also places added strains on human resources personnel, hiring managers and supervisors who must constantly find and bring new employees on board.

Workforce planning

Overlap with one's predecessor, especially one with an exceptional institutional memory, is important given the complex nature of FDA's work. It can often take one to three years for a new employee to be brought up to speed on many key issues, and when experienced people leave, the agency is seriously at risk. During a discussion group with representatives from several centers, a career manager explained: "If I have an expert on listeria, when there's an outbreak on listeria, I can't hire anyone additional. We are one deep in too many places and can't bring

people along because we don't have authority to hire. We have no one to backfill because we haven't been able to hire and train three to five years in advance. We know people are leaving but can't hire for their position until they leave."

Job training

As a regulatory agency, there is no university or school to teach FDA employees how to do their jobs. As one FDA scientist put it, "The learning curve is more of a mountain than a curve." The training required is intensive, and it needs to happen within various FDA offices. We found from individual interviews that "every group is different," but that coming to work at the FDA is a bit of a learn-as-you-go process. The smaller the group, the easier it is to put together better training. At some centers, such as CDRH, a training and mentoring program was recently put in place that includes specifics about what regulations to follow, what to do and where to go for resources, and how to handle a particular situation or problem. Content areas include medical device law, regulatory writing, risk communication, time management and problem solving. However, the success of this program has not yet been measured. One good sign is that some of the seasoned employees have been asking if they can participate in the training. But even when there are developmental and training programs in place, the main challenge is the ability of staff to utilize these opportunities. The workload is so high that people often have to make a decision between more training and getting their work done.

Professional development

For scientists, keeping up with changes and advancements in their field is of utmost importance. This often requires attending professional meetings, presenting at conferences, being a part of active conversa-

tions with colleagues, and engaging in forums where they can enhance FDA recruitment pipelines and scientific knowledge. FDA officials are aware of the need in this area. Chief Scientist Dr. Jesse Goodman, for example, has recognized the benefits of ongoing professional development for the FDA's current STEMM employees and as a recruiting tool for attracting new talent. He created the Office of Scientific Development to serve as a focal point to develop opportunities in the workplace for learning. His chief message to FDA scientists: "You are important." Nevertheless, progress remains insufficient. Lack of funding and heavy workloads have constrained many FDA scientists from attending professional conferences or other meetings, lowering morale among the staff, according to our interviews.

In some field offices, it was reported that staff members are discouraged by supervisors from attending professional conferences altogether and, if they push the issue, are required to provide pages of written justifications. Professional development is an area of constant struggle. The presidential Executive Order 13589, Promoting Efficient Spending, issued on Nov. 9, 2011, encourages strategic alternatives to government travel and in some instances has been interpreted to discourage travel to conferences. Officially, the FDA reports that it supports professional development by allowing staff during working hours to teach, conduct research or participate in clinical activities. The agency said FDA staff has up to eight hours per week to participate in professional development and cited as examples physicians working at the Bethesda Naval Hospital to maintain their clinical skills or scientists teaching at area universities.

FDA officials also said that, depending on available funding, agency staff members have opportunities to attend external conferences and

meetings every year. Examples cited were conferences and meetings sponsored by the Society of Toxicology, the American Society of Therapy and the American Society of Clinical Oncologists. An agency official said FDA staff members attend conferences and meetings sponsored by trade organizations such as the Drug Information Association and the Medical Device Manufacturers Association.

REALITIES OF GOVERNMENT SERVICE

Pay/budget issues

Pay freezes, lack of raises and retention bonuses, and budget uncertainty represent huge challenges for the FDA. Professionals in STEMM fields can often earn more money in private industry, and that has been a perennial problem. It also has become clear that most centers do not offer signing bonuses or relocation funds. For those who join the FDA for its mission, programmatic budget cutbacks put a real strain on the resources needed to meet basic job requirements. From the workforce planning perspective, the uncertainty over the budget makes planning for hiring and backfilling vacated positions extraordinarily difficult.

FDA officials also must deal with current political realities, which have led to an increasing reliance on industry user fees to fund operations. While the various industries, including the pharmaceutical and medical device companies, provide large sums to the agency, they also negotiate and in many ways influence how the FDA will spend the money. In the case of pharmaceuticals, for example, congressionally approved agreements negotiated between the FDA and the industry set the number of people to be hired for new drug reviews, timelines for reviews and approvals, and other detailed aspects of the work process.

The conditions created by the user fee system have distorted the structure of the FDA's workforce, creating the potential for expertise gaps in some areas even as other roles are better staffed.

The FDA's fiscal 2013 budget contains seven user fee programs that account for about \$2 billion in industry funding, or roughly 44 percent of the entire agency budget.

Competition

The FDA faces fierce competition for top candidates in the science and technical fields from private industry, which can offer more attractive salaries, and from other government agencies. The key to attracting the right people is to focus on the tools FDA offers—the learning opportunities, the immediate impact and the opportunity to improve public health and make a difference in people's lives.

FDA AT A GLANCE

THE STORY BY THE NUMBERS

Overall, the FDA has a highly educated and highly compensated workforce relative to many other federal agencies, a sizable portion of which does not consist of permanent positions. The organization has 14,824 employees, with 10,826 listed as full-time, nonseasonal permanent employees. About one in five employees work in consumer safety, and one in six are medical officers, a position that requires an M.D. at the minimum.

Looking at just the full-time, permanent workforce, more than half of the employees are in the GS-13 to -15 range and about half (48 percent) earn more than \$100,000.² There are few recent college graduates at the agency since most positions require more than just an undergraduate degree. Forty percent of the permanent workforce have a master's degree or higher. The age distribution at FDA resembles a bell curve, with 58 percent of the workforce between the ages of 40 and 60. The average age of an FDA employee is 47, with 43 percent below the age of 45.

² This definition of adjusted basic pay comes from FedScope data and is defined as follows: The sum of an employee's rate of basic pay and any locality comparability payment and/or special pay adjustment for law enforcement officers. An employee's actual earnings may be more or less than the annualized rate because of factors such as overtime, shift differentials, less than full-time work or leave without pay.

The temporary or term-appointment employees are slightly older and are paid slightly more than their full-time permanent counterparts, on average. Temporary employees have an average salary of \$113,937 and an average age of 49. They are also more highly educated, with 76 percent having a master's degree or higher—36 percent higher than that of the full-time permanent workforce.³

The FDA has defined medical and scientific positions as mission-critical, meaning they are essential to strengthening its public health mission. Two-thirds of all FDA positions fall into the mission-critical category, and 15 of the 16 mission-critical occupations are in science or engineering. The top occupations filled in fiscal 2010 were medical officers (360), consumer safety officers (326), and chemists (101). Startlingly, fully 8 in 10 of medical officers at the FDA are temporary or term appointed employees. Medical officers are doctors of medicine involved in ensuring the safety of drugs, vaccines, medical devices, blood products and food. They come into the FDA at the GS-14 or -15 levels. Consumer safety officers, who are also referred to as investigators and inspectors, investigate complaints of injury, illness or death caused

³ The education data disclosed by OPM is not necessarily updated if a person obtains a degree while hired, which could mean that the data included in this report for the permanent workforce are slightly lower.

Profile of the FDA workforce, fiscal 2010

Total number of employees	14,824 (73 percent, or 10,826 employees, are categorized as full-time, nonseasonal permanent)
Pay	The average employee makes \$103,529 a year. Fifty-six percent make over \$100,000 a year. Government-wide, the average federal employee earns \$74,302 a year and 21 percent earn over \$100,000 a year.
Federal tenure	The average FDA employee has served in the federal government for 12 years. Twenty-eight percent have served less than 3 years in the federal government. The average federal employee has served 13 years with 22 percent having served less than 3 years in government.
Retirement eligibility among permanent workforce	14 percent eligible to retire by fiscal 2010 (14 percent government-wide) 22 percent eligible to retire by fiscal 2013 (25 percent government-wide) 28 percent eligible to retire by fiscal 2015 (32 percent government-wide)
Retirement eligibility among FDA's 55-person Senior Executive Service	44 percent eligible to retire by fiscal 2010 (36 percent government-wide) 49 percent eligible to retire by fiscal 2013 (53 percent government-wide) 60 percent eligible to retire by fiscal 2015 (64 percent government-wide)

Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

by FDA regulated products, initiate actions against violators, advise industry on enforcement policies and develop inspection procedures and techniques. Consumer safety officer positions can range from the GS-5 to the GS-13 level.

Each center faces its own unique workforce challenges and often competes with others for top candidates, depending on the positions it needs to fill. CDER and ORA account for half of the workforce, given their mission of minimizing exposure to unsafe, ineffective and poor quality drugs, and then making sure that the manufacturers are carrying out all recommendations in these areas. One-seventh (14 percent) of the FDA's employees are located at CDRH, while just about 8 percent are employed at CBER.

ORA has the youngest employees on average, at 44 years old, while CDRH and CBER have the most senior employees among the centers with an average age of 51 years old each.

When looking at pay across the four centers and the FDA overall, CDER, CBER and CDRH have similar salary distributions, with less than 10 percent of their employees earning under \$50,000 per year

and more than 60 percent earning above \$100,000 per year. The highest paid employees on average reside at CDER and CBER, with 12 percent and 11 percent of the workforce earning \$150,000 or more, outpacing CDRH and ORA, where 6 and 0.6 percent of employees earn above \$150,000, respectively.

Fifty-five percent of employees are either part-time, term-appointed or temporary employees at CDRH. Forty-one percent of employees at CDER and 36 percent of CBER's workforce also fall into the temporary employee category. Conversely, at ORA, 96 percent are full-time, nonseasonal permanent employees.

Attrition at the centers

Attrition is of concern since it can take between one and three years to get newly hired STEMM talent up to speed on their jobs. CDRH has an attrition rate of 9.7 percent, by far the highest among the centers. CBER has the second highest rate at 7.5 percent, and CDER is third at 6.8 percent. The reason is largely explained by the type of employees the centers have on payroll. Those centers with the largest percentage of temporary employees, which also consist of temporary and term-appointed employees, are going to have higher attrition rates than those who hire a permanent workforce.

WORKFORCE DEFINITIONS

Workforce definitions used throughout this report reflect the way that federal agencies define the data from the Central Personnel Data File, FedScope and the Federal Employee Viewpoint Survey: *Permanent workforce* refers to permanent, full-time, nonseasonal federal employees. Due to data availability, the permanent workforce in this report does not include the Commissioned Corps Officers. The permanent workforce is important when looking at employee retention because they are employees that could develop inside the organization. *Temporary workforce* refers to federal employees who are *not* full-time, nonseasonal and permanent. This includes part-time employees and at the FDA many individuals who are hired for two- to four-year term appointments. This group is significant because with many employees hired into temporary positions, there is planned attrition. This may not be all bad or all good but is important to consider when examining the entire FDA workforce. *Total workforce* includes both permanent and temporary federal employees. Due to data availability, the total workforce still does not include Commissioned Corps Officers. It also does not include employees of federal contractors who may work on-site at the FDA.

Top five mission-critical occupations at the FDA by number employed, fiscal 2010

	Number employed	% of temporary employees
Consumer safety officer	2,904	1
Medical officer	2,310	80
Chemist	1,105	13
Biologist	675	35
Microbiologist	629	16

Profile of targeted FDA centers, fiscal 2010

Together, the Center for Drug Evaluation and Research, Office of Regulatory Affairs, Center for Devices and Radiological Health and Center for Biologics Evaluation and Research account for three-quarters of the FDA's entire workforce.

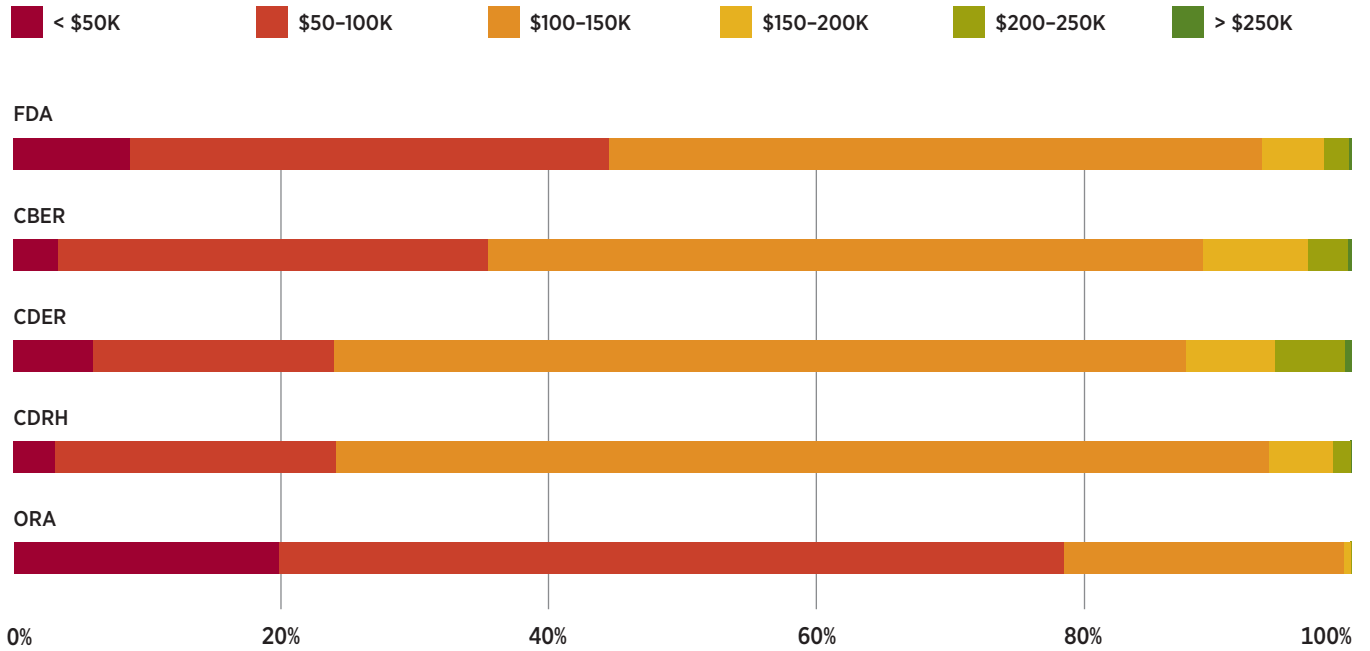
	Total number of employees	% of FDA workforce	Average age
CDER	3,926	26	49
CDRH	2,132	14	51
ORA	3,775	26	44
TOTAL	10,993	74	

FDA center attrition rates, fiscal 2010

	% of permanent employees	% of total employees
CDER	2.5	6.8
CDRH	5.8	9.7
ORA	4.2	5.7

Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

Percentage of workforce by annual pay, fiscal 2010



Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

The Office of Regulatory Affairs plays a different role than the other centers

The marked differences between ORA and the other FDA centers included in this study regarding average salary, tenure, geographic distribution and age require some explanation.

The ORA is the lead office for FDA field activities and focuses on imports, inspections and enforcement policy. In this capacity, ORA supports the five FDA centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products and reviewing products offered for entry into the United States. More than 85 percent of ORA's staff works in five regional offices, 20 district offices, 13 laboratories, and more than 150 resident posts and border stations. ORA headquarters comprises the Office of Resource Management; the Office of Regional Operations; the Office of Enforcement and the Office of Criminal Investigations. FDA maintains offices and staff in Washington, DC; the U.S. Virgin Islands; Puerto Rico and in all U.S. states except Wyoming.

The ORA differs considerably from the centers in terms of salary. The centers have a large number of highly paid doctors and scientists, while ORA has a significant number of investigators, inspectors and enforcement personnel, and a much smaller percentage of the workforce making above \$100,000.

In terms of geographic dispersion, 73 percent of FDA's workforce is located in the Washington, DC, metropolitan area, while the vast majority of ORA personnel, as noted above, are located throughout the country. This suggests that ORA and its management are confronting a unique set of additional challenges, such as recruiting talent into different environments, long-distance coordination, ensuring the staff is rewarded fairly despite geographic separation and preventing a sense of employee isolation.

The ORA also differs in comparison to the other centers in terms of federal tenure. The ORA has a higher overall percentage of employees whose length of federal service is 20 to 30 years, and it has the largest percentage of employees who have been in federal service for more than 30 years. At the same time, ORA employees have an average age of 44, compared to the averages of 51, 51 and 49 at CDRH, CBER and CDER, respectively.

The growth of the FDA workforce since 2007 has impacted the individual centers differently. CDER, currently the largest of the centers, hired 2,021 employees from fiscal 2007 to 2010; CBER, currently the smallest of the centers, hired 441 employees since that time, and ORA and CDRH have hired 1,728 and 1,056, respectively. The majority of ORA's new employees filled full-time permanent positions, with more than 80 percent each year hired in that capacity. The opposite is true at CDRH, where, on average, over 80 percent of newly hired employees did not join as permanent employees. CBER is the most balanced of the centers, with just about as many newly hired workers coming on board as temporary personnel. Since 2007, about 40 percent of CDER's new employees were hired as full-time permanent positions.

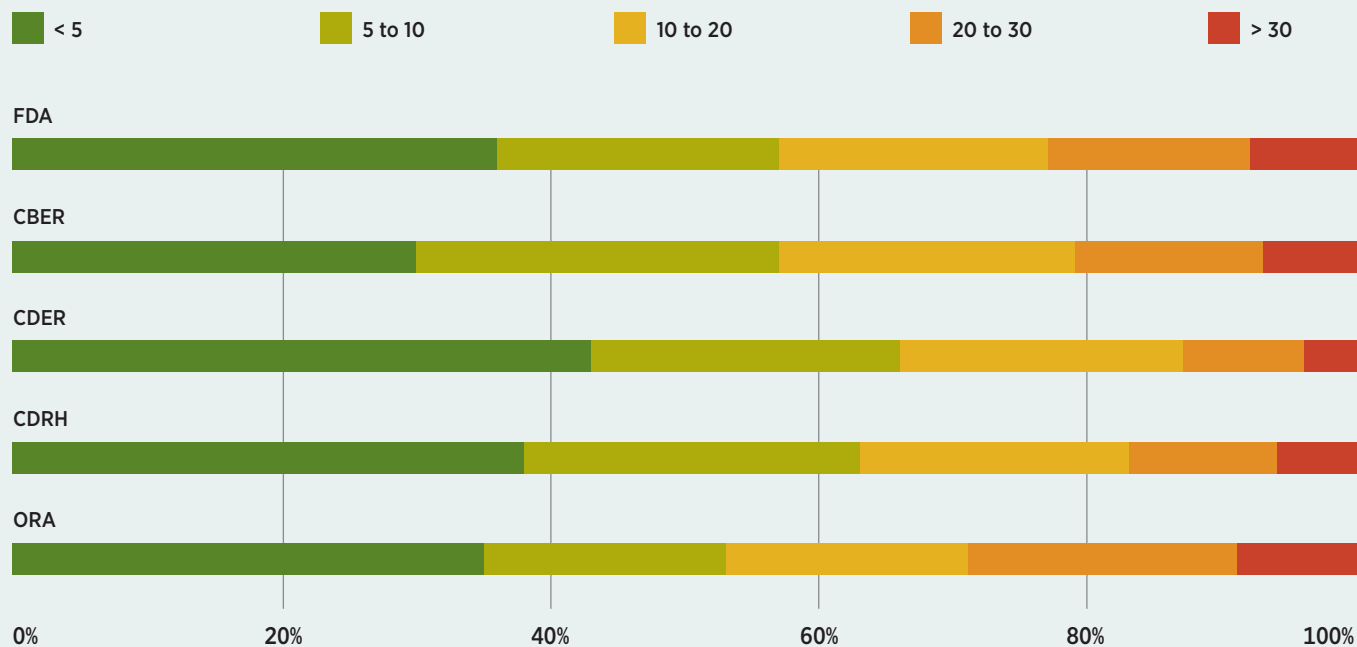
Number of temporary employees versus permanent employees by center

	Workforce in fiscal 2010			
	Temporary	Full-time permanent	Total	% temporary
CBER	414	746	1,160	36
CDER	1,615	2,311	3,926	41
CDRH	1,162	970	2,132	55
ORA	155	3,620	3,775	4

New hires and percentage hired to permanent positions by center

	Total hires in fiscal 2010	% of permanent new hires
CBER	102	51.0
CDER	528	35.8
CDRH	396	17.9
ORA	566	83.2

Years of federal service in FDA centers



Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

BEST PLACES TO WORK OVERVIEW AND ANALYSIS

The *Best Places to Work in the Federal Government*[®] rankings produced by the Partnership for Public Service offer the most comprehensive assessment of federal employee satisfaction and commitment, two necessary ingredients in developing high-performing organizations and attracting top talent.

Based on an analysis of data obtained from the Office of Personnel Management's (OPM) Federal Employee Viewpoint Survey, the *Best Places to Work* rankings offer a government-wide view as well as an examination of individual agencies and their subcomponents regarding how federal employees perceive their jobs and agencies.⁴

The analysis provides insights in 10 workplace categories, such as effective leadership, employee skills/mis- sion match, teamwork, pay and work/life balance.

There is nothing more revealing than what employ- ees have to say about their workplaces. When agencies are badly managed and workers are unhappy, a low level of engagement and poor performance often follow. The *Best Places to Work* rankings provide a mechanism to

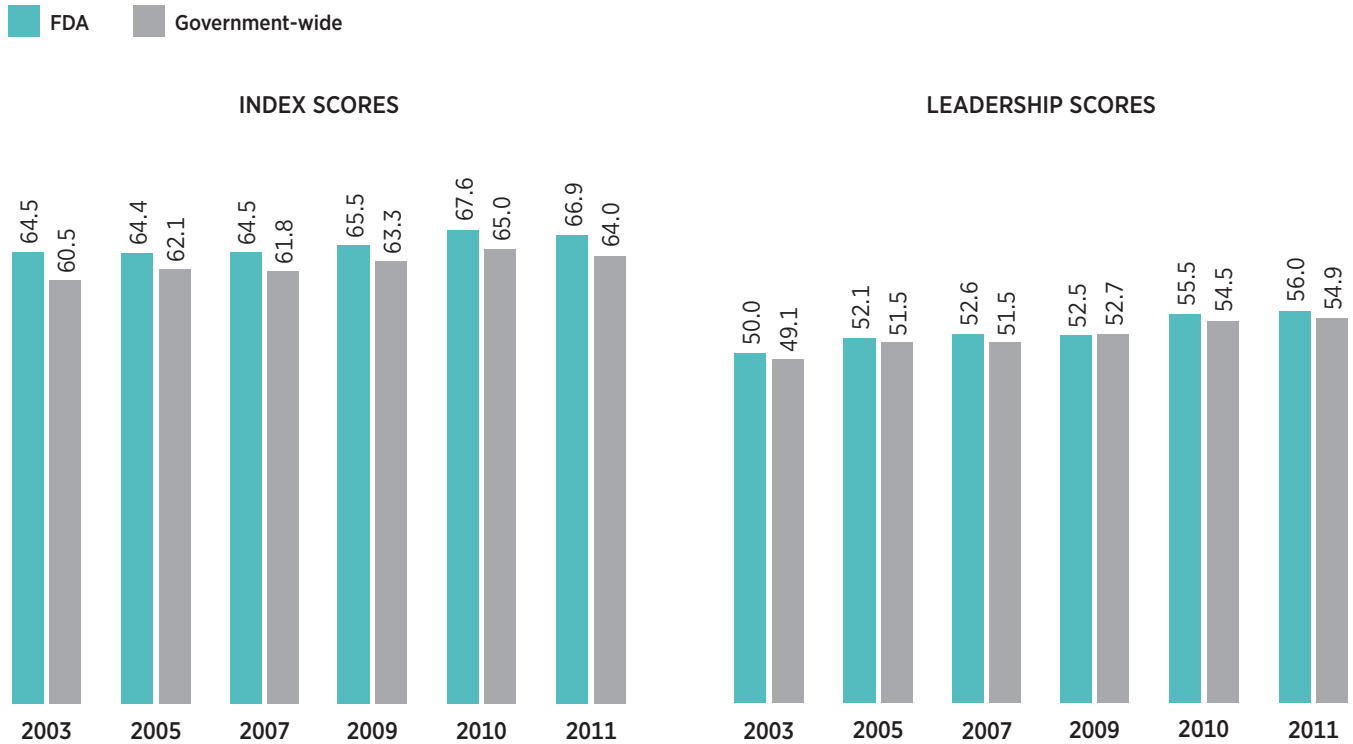
hold agency leaders accountable for the health of their organizations, provide warning signs of trouble and offer a roadmap for improvement.

In 2011, the FDA received an employee job satisfac- tion and commitment score of 66.9 out of a total of 100. This placed FDA third among the HHS subcomponents, behind the top-ranked Administration on Aging, with a score of 73.5, and the National Institutes of Health, with a score of 68.5. It ranked just ahead of the Centers for Disease Control and Prevention (66.1), the Health Re- sources and Services Administration (65.3), the Agency for Healthcare Research and Quality (63.6), the Centers for Medicare and Medicaid Services (61.6), the Admin- istration for Children and Families (57.7), Indian Health Services (56.4), the Office of the Secretary of HHS (53.8), and the Substance Abuse and Mental Health Services Ad- ministration (51.9).

The FDA also ranked 73 out of 240 federal agency subcomponents. Its score is higher than the government- wide average but well below the top-tier subcomponents such as the Environment and Natural Resources Division of the Department of Justice (81.5) and far higher than

⁴ The Federal Employee Viewpoint Survey analyzed in the *Best Places to Work in the Federal Government*[®] rankings is administered only to full-time, permanent employees. Unless otherwise specified, the sat- isfaction of the temporary and Commissioned Corps employees at the FDA is not included in this analysis.

Best Places to Work scores



the Office of the Chief Procurement Officer at HUD, which had a score of 37.0.⁵

To better understand an organization's overall employee satisfaction and commitment score, the Partnership does two key analyses of the employee data. First it looks at employee responses to questions in 10 workplace categories. These categories, identified in the table on page 18, provide a representation of workplace environment issues captured in the OPM survey.

The Partnership then analyzes the relationship between the employee responses to the questions in the 10 workplace categories, with responses to the satisfaction and commitment survey questions, to determine which workplace issues

are driving employee satisfaction responses.

In the case of the FDA, responses to overall leadership, a match between skills and mission, and pay are closely linked to the level of satisfaction and commitment voiced by employees. These factors are also the same key drivers of employees government-wide.

Of the 10 workplace categories, FDA employees feel most positive about employee skill/mission match, teamwork and the effectiveness of supervisors. These categories are viewed as positive by employees government-wide. In comparing FDA's scores to government-wide scores, FDA employees view strategic management and teamwork more positively than responses government-wide, but are less positive on issues of pay and performance-based rewards and advancement.

FDA's leadership scores

The effective leadership category measures the extent to which employees believe leadership at all levels of the organization generates motivation and commitment, encourages integrity and manages people fairly, while also promoting the professional development, creativity and empowerment of employees.

While many factors are involved in shaping how employees view their workplace, the 2011 *Best Places to Work* analysis for the sixth time in a row showed the primary driver of employee satisfaction and commitment in the federal space is effective leadership, and in particular, senior leadership.

FDA employees have been more satisfied with their leaders than the rest of government since the first *Best Places to Work* rankings in 2003. Except for a very slight dip in 2009, employee satisfaction with FDA

⁵ To see the full *Best Places to Work in the Federal Government*® rankings, please visit bestplacestowork.org

leadership has been on an excellent trajectory.

Because of the importance of leadership to employee satisfaction and commitment, the Partnership divides the effective leadership category into four different sub-categories (senior leaders, supervisors, empowerment and fairness) to help agencies interpret the findings more precisely. The scores for senior leaders and supervisors, for example, tend to differ. The senior leader category measures the level of respect employees have for senior leaders, satisfaction with the amount of information provided by management and perceptions about senior leaders' honesty, integrity and ability to motivate employees. The supervisor category measures employees' opinions about their immediate supervisor's job performance, as well as how well supervisors give employees the opportunity to demonstrate leader-

ship skills, support employee development and provide useful feedback about job performance. The empowerment category measures the extent to which employees feel empowered with respect to work processes and how satisfied they are with their involvement in decisions that affect their work. The fairness category measures the extent to which employees believe arbitrary action and personal favoritism is tolerated and if employees feel comfortable reporting illegal activity without fear of reprisal.

In 2011, FDA employees were more satisfied with three of the four leadership sub-categories compared with employees government-wide, excepting the issue of fairness. Although employee satisfaction with fairness has improved dramatically both at the FDA and government-wide from 2007 to 2010, it declined at the FDA from 2010 to 2011, wid-

ening the gap between the agency and the government as a whole.

On the issue of pay, FDA's employee satisfaction score dropped 8.4 percent from 2010 to 2011. This decrease is slightly higher than the government-wide decrease of 6.1 percent and coincides with a government pay freeze which did apply at FDA.

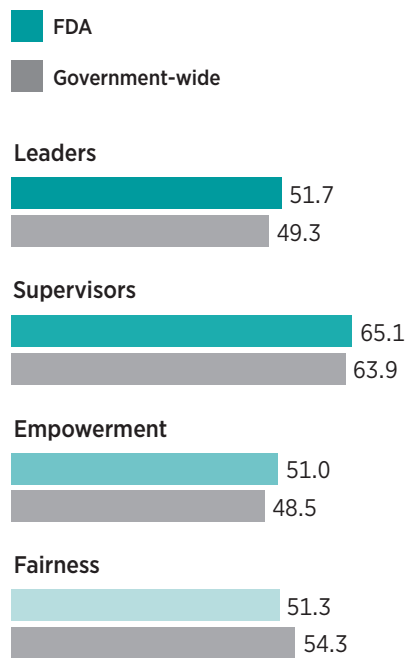
Our *Best Places to Work* analysis also looked at the issue of gender. Men are more satisfied than women at FDA, and the difference between the percentage of men who are satisfied and the percentage of women who are satisfied is substantially larger at the FDA than in government as a whole. Although the gender satisfaction gap has been decreasing at the FDA since 2008, it is still greater than 2 percent, while government-wide, women are more satisfied than men.

2011 Best Places to Work scores: FDA and government-wide

	FDA			Government-wide	
	Score	% change from 2010 to 2011	2011 Best Places to Work rank*	Score	% change from 2010 to 2011
Best Places to Work Index	66.9	-1.0	73	64.0	-1.5
Employee Skills/Mission Match	78.4	-0.3	109	78.6	-0.3
Teamwork	68.3	2.6	77	65.3	0.1
Work/Life Balance	61.9	-0.8	122	60.2	-0.9
Training and Development	60.7	-2.1	112	60.7	-0.7
Strategic Management	60.1	0.2	62	56.8	0.8
Support for Diversity	58.9	0.5	116	57.8	1.5
Pay	58.1	-8.4	171	59.1	-6.1
Effective Leadership	56.0	0.8	123	54.9	0.7
Leaders	51.7	3.7	99	49.3	0.7
Supervisors	65.1	-0.9	129	63.9	0.9
Empowerment	51.0	0.5	108	48.5	-1.2
Fairness	51.3	-0.2	161	54.3	1.8
Performance-Based Rewards and Advancement	46.4	0.0	140	45.9	-1.1
Family-Friendly Culture and Benefits	41.6	-1.7	81	33.6	-7.3

* 2011 Best Places to Work Index Score rankings for subcomponents were out of 240; category scores were out of 228.

2011 Best Places to Work scores in leadership sub-categories



Overall, we found that the most satisfied demographic groups at the FDA (compared to other HHS sub-components) are whites, males and those under 40 years of age. These groups at FDA have higher satisfaction scores than at least 70 percent of other HHS sub-components that could be ranked.

FDA's workforce environment

Retaining highly qualified talent is a matter of tremendous concern in light of severe budget constraints and hiring freezes that limit an agency's ability to hire new or replace departing employees. Agencies such as FDA have the added challenge of competing with the private sector for top STEMM-educated and -trained talent. Thus, agencies must pay close attention to who is leaving and why, focusing on ensuring that they have created a workplace culture and environment that will help

retain their best employees. Well designed and targeted retention strategies begin with understanding who is leaving the agency, why they are leaving, what retention techniques are currently being used by the agency and whether these strategies are addressing root workplace environment issues.

The Partnership uses 18 questions from the Federal Employee Viewpoint Survey in addition to the issue of pay to help understand which workplace issues influence an individual's intent to stay or leave his or her job.

Regardless of whether an FDA employee plans to leave or stay, our analysis showed that five issues consistently receive the lowest satisfaction scores. FDA employees are least satisfied with the opportunity for a better job within their organization, the recognition they receive for doing a good job and the information

FDA Best Places to Work satisfaction scores in leadership subcategories

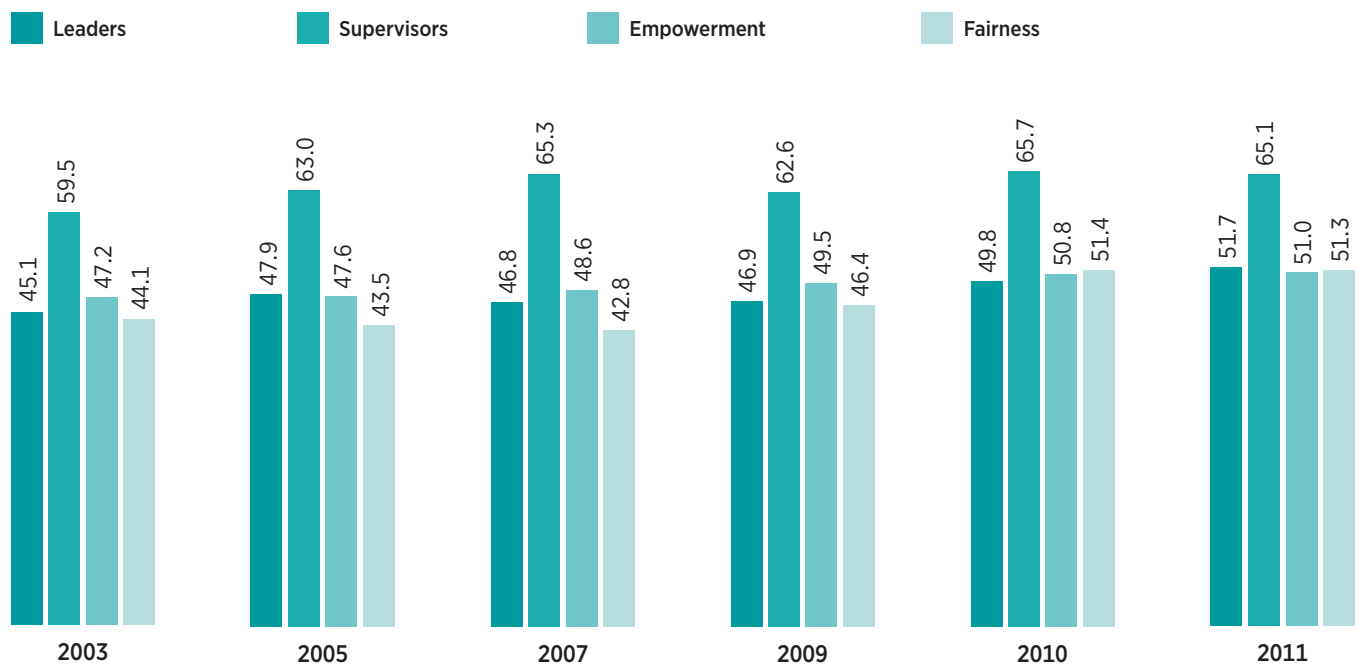


TABLE 8

Percentage of positive responses for select workplace satisfaction questions

	FDA	CBER	CDER	CDRH	ORA	Com. Corps
Total respondents	4,928	388	1,318	388	1,337	467
2011 Federal Employee Viewpoint Survey Questions	% positive responses	% positive responses	% positive responses	% positive responses	% positive responses	% positive responses
I have sufficient resources (for example, people, materials, budget) to get my job done.	50.5	60.8	56.7	44.3	47.3	61.5
My workload is reasonable.	59.7	70.4	57.5	49.7	61.9	67.5
My training needs are assessed.	51.4	64.4	55.0	46.9	51.2	59.7
The skill level in my work unit has improved in the past year.	56.9	61.1	59.7	56.2	56.5	62.3
How would you rate the overall quality of work done by your work unit?	84.9	89.2	88.6	87.4	81.3	89.1
The workforce has the job-relevant knowledge and skills necessary to accomplish organizational goals.	73.5	83.0	81.1	72.9	70.2	80.1
My organization's leaders maintain high standards of honesty and integrity.	57.9	69.6	71.3	59.5	50.3	68.3
Managers/supervisors/team leaders work well with employees of different backgrounds.	62.2	70.9	73.9	69.3	52.6	73.7
How satisfied are you with the information you receive from management on what's going on in your organization?	48.7	56.2	59.2	52.1	42.7	60.0
How satisfied are you with the recognition you receive for doing a good job?	48.9	60.1	56.8	48.7	43.9	55.2
How satisfied are you with the policies and practices of your senior leaders?	45.5	55.9	57.0	46.9	37.4	56.5
How satisfied are you with your opportunity to get a better job in your organization?	40.3	46.6	46.4	46.6	36.3	52.7
Considering everything, how satisfied are you with your job?	69.0	79.1	78.8	74.7	65.8	80.1

Source: The Office of Personnel Management's 2011 Federal Employee Viewpoint Survey

they receive from management on what is going on within their organization. They give lower scores on the level of respect for their organization's senior leaders and how well their talents are used in the workplace. Satisfaction with pay is not one of the issues with which FDA employees expressed the most dissatisfaction.

Although the responses of those planning to stay at the FDA are more positive, in general, than the group that plans to leave, it is revealing that only about half of those planning to stay are satisfied with their opportu-

nity to get a better job within their organization.

Job and career advancement clearly is a major sticking point of FDA employees. This suggests management should pay close attention to enhancing the training and development of its staff and provide opportunities for employee development.

Overall satisfaction: Center comparisons on specific questions

There are some distinct satisfaction differences among the centers on a variety of issues. The largest differences are among employees at

CDRH and ORA, who are far less satisfied in terms of having the resources to get their jobs done, having a reasonable workload, addressing training needs and believing that the organizations' leaders maintain high standards of honesty and integrity. Members of the Commissioned Corps and employees at CBER tend to give higher scores on these measures.⁶

⁶ The FDA granted us special permission to use the 2011 FEVS Public Health Service Commissioned Corps data only for this *Best Places to Work* analysis.

UNDERSTANDING ATTRITION AT FDA

On the surface, FDA has a lower attrition rate compared with the government-wide average, although the gap has narrowed considerably since 2007. The government-wide attrition rate for 2007 to 2010 has fluctuated with the overall health of the U.S. economy but has decreased, while attrition of the FDA's permanent workforce has grown slightly.⁷ Still, the FDA remains below the government-wide attrition rate by 1.8 percentage points.

These attrition percentages tell only part of the story. As we discussed in chapter two, unlike many other agencies, FDA has a high number of term-appointed employees. As a result, FDA must pay attention to the full attrition picture, including those hired for a limited period of time since these employees perform mission-critical functions as well. In fiscal 2010, FDA lost 7.2 percent (1,128 individuals) of its total workforce (full-time, permanent employees and term-appointed employees)⁸, nearly half (46 percent) of these because their temporary appointment ended. With such a large percentage

of FDA's losses anticipated, the agency is in a position to plan for and effectively transition a key portion of its workforce. Nonetheless, this high turnover places tremendous pressure on the recruiting and hiring process and can have a detrimental impact on the stable workforce that must constantly absorb and manage change while trying to meet increasingly challenging and complex mission requirements.

In addition to those whose term appointments expired, 21 percent retired, 25 percent quit the government altogether and 5 percent transferred to another federal agency.

Of the 434 full-time permanent staff who left FDA in 2010, 29 percent quit the government, 13 percent transferred to another government agency and half (52 percent) retired.

Attrition in key STEM occupations

Apart from temporary administrative positions, the top occupations experiencing personnel losses at FDA in 2010 were medical officers (175), consumer safety officers (131) and chemists (53). As the table on page 22 illustrates, biomedical engineer, general engineer and statistician are three occupations with higher attrition at the FDA compared with EPA, the Centers for Disease Control and Prevention, the NIH and government-wide excluding the Department of Defense.

⁷ The attrition rate in this report refers to the percent of all employees who left the agency at some point during the fiscal year. This is to be consistent with the definition of attrition in the FDA Strategic Human Capital Plan.

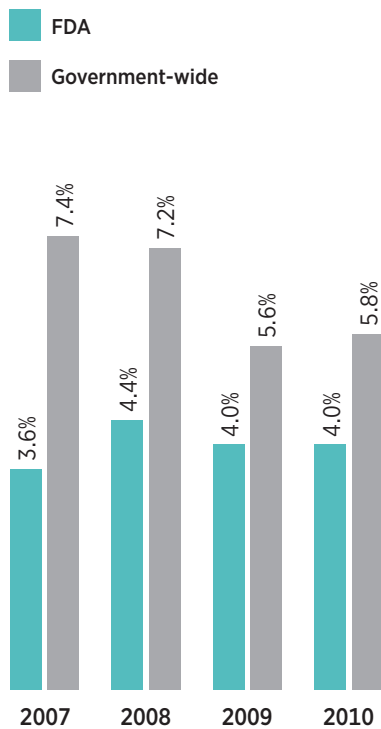
⁸ Due to data availability, transfers within the Department of Health and Human Services (e.g., from FDA to CDC) or within the FDA (from CDER to CBER) are not included in this number.

Attrition of mission-critical occupations at the FDA and comparable agencies in fiscal 2010

	FDA		EPA		NIH		CDC		Government-wide	
	Total employed	Attrition rate	Total employed	Attrition rate	Total employed	Attrition rate	Total employed	Attrition rate	Total employed	Attrition rate
Statistician	37	12.8	74	9.0	70	6.8	211	3.2	3,366	6.1
General engineer	42	9.1	57	1.8	49	6.0	76	0.0	24,729	4.3
Veterinary medical officer	116	7.6	18	10.0	75	5.1	22	0.0	2,227	5.8
General health scientist/ Regulatory project manager/Epidemiologist	627	7.4	184	5.8	2,455	5.4	1,767	8.4	11,443	7.3
Medical officer	2,310	7.0	23	8.0	1,745	10.7	363	8.9	29,985	8.6
Operations research analyst	48	6.4	9	11.1	4	0.0	8	0.0	4,482	5.0
Biomedical engineer	194	6.2	2	0.0	39	4.8	7	0.0	597	6.4
Microbiologist	629	4.6	107	5.3	409	6.1	477	2.6	2,629	4.9
Chemist	1,105	4.5	578	3.1	563	6.7	185	3.6	5,892	5.3
Consumer safety officer	2,904	4.3	0	0.0	1	0.0	0	0.0	3,305	4.4
Biologist	675	3.6	1,097	5.0	2,571	6.8	330	4.9	21,472	5.5
Pharmacologist	417	3.1	33	5.9	111	12.0	0	0.0	619	6.0
Mathematical statistician	296	3.0	34	2.8	100	2.0	119	3.2	1,482	5.4
Pharmacist	196	2.5	0	0.0	94	6.0	0	0.0	8,744	8.6
Toxicologist	85	1.2	251	4.1	49	7.5	19	8.7	506	4.7

Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

Attrition trends of the permanent workforce by fiscal year



Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

New hire attrition—a snapshot of those hired in 2008

In fiscal 2008, the FDA hired 1,748 individuals. Nearly half of these newly hired employees (818 people) were hired through temporary or term appointments, and half filled full-time, nonseasonal permanent positions (898 people).

Of those 898 full-time, non-seasonal permanent employees, 110 employees, or 12 percent, left the agency by the end of fiscal 2010. Of those who left, 64 percent resigned, 23 percent transferred to another federal agency, and two were terminated for poor performance during the one-year probationary period. Two-thirds of the 110 employees left within their first year—and a majority of those people (71 percent) resigned. Pharmacists and consumer safety officers were the two occupations with the highest attrition during this period. These data suggest the need for a deeper look at the recruitment, selection and onboarding processes at FDA.

Attrition of full-time, nonseasonal permanent employees hired by the FDA in fiscal 2008

The table on page 24 details the attrition for new hires in parts of the permanent workforce. Consumer safety and pharmacists had particularly high new hire attrition.

Retirement at the FDA

While most federal employees do not retire immediately upon becoming eligible, recognizing potential workforce risks, including loss of key institutional memory, is extremely important for an agency like the FDA. Planning for the near future and succession is especially important for a regulatory body that often needs up to three years to train qualified employees. Retirement eligibility is based on age and length of service in the federal government. (Retirement eligibility in this analysis refers to the percent of full-time, nonseason-

al permanent workers who have the right to retire with full benefits.)

The data shows that only 14 percent of the permanent FDA workforce overall was eligible to retire at the end of fiscal 2010. Even looking three to five years into the future, a smaller proportion of the FDA workforce is eligible to retire compared to the EPA or government-wide. However, this picture changes when looking at specific centers and occupations.

Of more concern is the Senior Executive Service (SES). The data reveals that 44 percent of FDA's 55 managers in the SES, were eligible to retire in 2010. This represented a larger proportion than the government-wide SES at 36 percent retirement eligibility. By 2015, 60 percent of FDA's senior executives will be eligible to retire, compared to 67 percent at the EPA. With so few career executives, FDA needs to ensure it has a strong SES pipeline and actively prepares for the retirements in these critical leadership positions.

Being eligible to retire, however, is different than planning to retire. The Federal Employee Viewpoint Survey asks respondents to answer the question of whether or not they are planning to retire. In 2011, 16 percent of FDA employees said they were planning to retire in five years or less, which is lower than government-wide SES, at 22 percent.

All employees who left FDA in fiscal 2010

	Total	% of total attrition	Full-time, nonseasonal permanent	% of permanent workforce who left
Left federal government	1,072	95	379	87
Quit	282	25	124	29
Retirement	237	21	224	52
Termination or removal (discipline/performance)	20	2	18	4
Expiration of employment	520	46	2	0.5
Death	13	1	11	3
Transfer to another agency	56	5	55	13
All attrition	1,128		434	

Attrition and retention rates of FDA permanent employees hired in fiscal 2008

	Permanent employees hired in 2008
Total number of new hires who left	110
Less than 0.5 years	25
0.5 to 1 year	40
1 to 1.5 years	18
1.5 to 2 years	16
2 or more years, but separated before end of fiscal 2010	11
Did not separate before end of fiscal 2010	788
Total number of new hires in 2008	898

Attrition of mission-critical employees hired in fiscal 2008, by occupation

	Permanent employees hired in 2008	% that left by 2010
Pharmacist	43	18.6
Consumer safety	319	14.4
Miscellaneous administration and program	64	14.1
General health science	44	13.6
Microbiology	36	11.1
Miscellaneous clerk and assistant	56	10.7
Management and program analysis	25	8.0
General natural resources management and biological scientist	26	7.7
Chemistry	67	6.0
Pharmacology	42	0.0

Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

AN ANALYSIS FDA STRATEGIC HUMAN CAPITAL PLAN

In a January 2010 report, Human Capital: Continued Opportunities Exist for FDA and OPM to Improve Oversight of Recruitment, Relocation, and Retention Incentives, the Government Accountability Office (GAO) concluded that the FDA “has faced challenges in obtaining the workforce needed to support its responsibilities, and similar to other agencies, has paid selected employees’ recruitment, relocation, and retention (3R) incentives.” However, the GAO report also noted that:

FDA’s employees in mission-critical occupations received the greatest number of 3R incentives from 2007 to 2009. However, without an updated strategic workforce plan or established agency-wide indicators for tracking its use of 3R incentives, FDA cannot assess the impact that these incentives have on its overall human capital strategy.

Since then, and with assistance from an outside contractor, the FDA developed comprehensive plans: Strategic Human Capital Plan 2010–2012 and the corresponding 2010 Workforce Analysis and 2011–2012 Workforce Plan. As part of the Partnership’s overall review and analysis of the FDA’s capabilities to recruit, hire, develop and retain well-qualified and motivated employees into STEMM occupations, we reviewed both plans and some related materials. It should be noted that there may be additional workforce planning documents as well as center-specific human capital plans. However, the analysis for our findings comes from the FDA agency-wide strategic human capital plan and the workforce plan, as they are the overarching guiding materials from which planning is guided. The following pages outline the findings from this analysis.

Strategic Human Capital Plan 2010–2012

- The FDA’s Strategic Human Capital Plan is a well-written overview intended to serve as an “overarching guide” to FDA centers and offices to ensure alignment with eight human capital goals, summarized as follows:
 1. Recruit a well-qualified workforce
 2. Develop an FDA-wide approach to train and develop employees
 3. Retain qualified employees to accomplish the FDA mission
 4. Improve workforce policies and practices
 5. Provide support to centers and offices via their human capital analysts
 6. Support diversity hiring initiatives
 7. Set human capital strategic direction
 8. Develop key leaders
- The FDA Strategic Human Capital Plan provides a useful analysis of several human capital challenges that hinder the agency’s ability to accomplish its goals. For example, the plan identifies problems such as FDA’s dissatisfaction with the quality of centralized shared HR services within HHS that is now undergoing a change to give power back to the FDA; an unacceptably long time to fill a position; the need to improve the quality of applicants referred to hiring managers; and the impact of two hiring “surges” in 2008 and 2009. Regarding the hiring surges, it is not-

ed that while the additions to the staff are welcomed, it takes about three years to train a new consumer safety officer (FDA's most populous occupation) to be fully effective.

- The hiring surges in 2008 and 2009 also raised a caution flag for FDA, particularly with regard to the consumer safety officer position, which accounted for more than 1,100 of the hires. The onboarding for such a significant percentage increase in staff is a challenge for any organization, and in the employee life cycle, attrition tends to be highest in the first one to three years after being hired. Even though overall turnover within the FDA has been relatively modest and manageable, special attention should be paid to turnover among new hires. The FDA is currently tracking occupation and organization, but adding years of service as a variable would be quite useful. Having made a substantial investment in acquiring new talent, the FDA will want to take whatever steps possible to maximize its return on that investment.
- The FDA Strategic Human Capital Plan also discusses some activities underway to address the identified problems. Appendix E to the FDA Strategic Human Capital Plan contains a number of specific performance measures relevant to each of the eight improvement goals. Many of the target dates for the performance measures have passed or will soon pass (e.g., by January 2012, develop a plan to fill 95 percent of vacancies by the end of fiscal 2012). It also discusses a number of the larger improvement efforts, such as the launch of an "HHS Accelerated Hiring Process" (AHP) that should have had time by now to demonstrate potential effectiveness. This means, of course, that the FDA has an opportunity to assess progress made (if it hasn't already) and to revise its improvement strategies based on an analysis of what has worked and what has not.
- The Strategic Human Capital Plan 2010–2012 was prepared at a time when the FDA had received a significant budget increase that allowed it to boost the size of its staff and to consolidate much of the staff in new state-of-the-art laboratories and offices at the White Oak, Maryland, campus. Since it will soon be time to update this forward-looking plan, it will be useful to use this opportunity to assess the impact of the federal budget situation and adjust the plan as needed.
- Appendix E to the Strategic Human Capital Plan contains an impressive list of strategic human capital goals, objectives and performance measures. It would have been even more impressive if there were a clear indication of which agency officials had pri-

mary responsibility and accountability for assuring that the goals and objectives are met. More specifically, there is no clear role or accountability for FDA managers outside of the HR function.

- The overall FDA Strategic Human Capital Plan doesn't cover all elements of an effective approach to workforce management. For example, it doesn't make any reference to employee onboarding practices. However, as noted above, the FDA developed this plan as guidance for the nine individual FDA centers and offices, which are expected to develop more tailored plans unique to their needs and workforce issues.
- The Partnership also reviewed a representative center plan, Center for Veterinary Medicine (CVM): Strategic Human Capital Plan, fiscal 2012–2016. The CVM plan provides a more specific discussion of CVM's human capital needs and outlines specific programs and initiatives, such as a year-long onboarding program intended to cultivate engagement and acculturation. Finally, the CVM plan outlines a number of specific improvement objectives and actions, including developing a "rotational program" to promote a holistic approach to learning and development. The main weakness in the CVM plan is that it doesn't provide specific target dates and performance measures for the strategic actions listed. In addition, as in the FDA-wide plan, there is no specific assignment of responsibility and accountability, and no defined role for individual managers to play.

2010 Workforce Analysis and 2011–2012 Workforce Plan

- The FDA's 189-page supplement to its overall Strategic Human Capital Plan is an effective response to the GAO's critique that without an updated strategic workforce plan, the FDA could not assess the impact of its improvement initiatives. This detailed workforce analysis identifies 17 mission-critical occupations for the FDA. They are:
 - Medical officer
 - Pharmacist
 - Consumer safety officer
 - Biologist
 - Chemist
 - Microbiologist
 - Pharmacologist
 - Mathematical statistician
 - Statistician
 - Epidemiologist

- Veterinary medical officer
 - General health scientist/Regulatory project manager
 - General engineer
 - Electrical engineer
 - Biomedical engineer
 - Toxicologist
 - Operations research analyst
- The Workforce Analysis plan provides information on the number of hires in each occupation and a breakdown by each center over a four-year period. It also provides a breakdown by:
- Years of service and age
 - Veterans
 - Gender
 - Race and national origin
 - Persons with disability
- The workforce analysis plan provides a useful and detailed analysis of loss/attrition, hiring and training, competency gaps and leadership positions. The FDA is to be commended for the work and analysis that went into this plan. The Partnership strongly urges the FDA to keep this plan up-to-date. The next few years will be crucial in determining whether or not the FDA is able to acquire, develop, motivate and retain the talent that will be essential to successful accomplishment of its vital mission. A current workforce analysis plan such as this one will be an extremely useful tool for the FDA. As noted earlier, paying special attention to turnover among the more than 20 percent of the workforce with less than five years of service in the FDA could be particularly valuable going forward.
- The workforce analysis plan appropriately pays particular attention to the approximately 13 percent of FDA employees who are in various leadership roles and notes the growing percentage of this segment is eligible for retirement. This leadership segment will also merit particular attention in the future as budget pressures reduce overall workforce growth and place added pressure on FDA leaders to manage effectively and efficiently.
- Another commendable aspect of the FDA workforce analysis plan is its focus on identifying the competencies—general and technical—needed by FDA employees. It also includes strategies for closing competency gaps via hiring and training activities. These

competency gaps are addressed along with 10 other identified gaps, e.g., lack of the desired balance in diversity and veterans in the workforce.

- Appendices C-1 through C-9 of the 2011–2012 Workforce Plan provide a discussion and analysis of the workforce needs, challenges and priorities for each of the nine centers and offices. Each appendix focuses on four main questions for the center or office and a summary of the answers to six interview questions.

The four main questions are:

- What is the top priority at the centers and offices for 2011 and 2012?
- Are significant program, mission, workforce or organization changes planned?
- Is the composition of the current workforce at the centers and offices the same as that needed in the future?
- What are the top HR challenges that impact mission accomplishment capability?

The six interview questions are:

- Do any component(s) of this center/office expect to see changes in mission?
- What elements are identified as the greatest challenges?
- What changes are expected in the workforce, skills, numbers or enabling technology?
- What are the issues associated with recruitment, retention and development?
- What additional tools, service and support are required to meet mission and workforce needs?
- What was the overall experience with the hiring surge?

The responses to these questions are enlightening and show a clear connection between various workforce challenges and the FDA's mission accomplishment capability. There were a number of common themes among all or most of the nine centers/offices. Chief among those was dissatisfaction with what is generally considered a broken hiring process (not too surprising given the hiring surge), which was considered to take too long and which too often did not deliver the quality of candidate needed. Consistent with that finding was related dissatisfaction with the quality of the HR services provided by a centralized HR staff in HHS, highlighted previously.

Now that more than a year has passed since this workforce analysis was conducted, it will be infor-

mative to determine what has changed and which of the improvement strategies outlined seems to be most productive. Also, if some centers seem more successful than others in overcoming identified obstacles, perhaps there are some lessons learned that can be shared.

One of the conclusions that can be drawn from this 2010 Workforce Analysis and the 2011-2012 Workforce Plan is that, to date, overall retention has not been nearly as challenging an issue as hiring has been, and as employee and leadership development will be in the future. As tightening budgets require that tough decisions be made and priorities set with regard to the FDA workforce, it will be crucial to have the type of thorough data and analysis contained in this report available and put to use. To be most useful, of course, it will need to be updated periodically and given top management attention. This plan provides a great foundation to build upon going forward.

Conclusions and recommendations

The FDA's 2010–2012 Strategic Human Capital Plan and the associated 2010 Workforce Analysis and 2011–2012 Workforce Plan are a good starting point. Their main strengths are twofold:

- They are thoughtful and well written, and should have provided a good “overarching guide” to FDA centers and offices to help in development of their own plans.
- Specific performance measures are included to gauge progress toward achieving the enumerated goals and objectives and addressing the identified challenges.

While the Partnership's review was underway, HHS announced it would begin the process of decentralizing some of the shared HR services that it provided and that are described in Appendix B of the Strategic Human Capital Plan. The quality and timeliness of some of those shared services from HHS are critiqued and identified as part of the FDA's strategic human capital challenges. The decentralization of some of those services will provide the FDA the opportunity to improve upon both quality and timeliness, but will surely provide its own challenges.

The FDA Strategic Human Capital Plan and Workforce Analysis are due to be updated. This is an especially propitious time since it provides the FDA with an excellent opportunity to reassess its workforce needs within a budgetary and operating environment that is likely to be very different going forward than it was when the current plans were developed.

FDA-EPA WORKFORCE COMPARISON

The Environmental Protection Agency (EPA) was selected as a comparison agency with FDA because of its public health mission, scientific capacity and regulatory function, and because it faces similar challenges in recruiting, developing and retaining a unique scientific workforce.

The FDA has about 4,000 fewer total employees than the EPA (14,824 versus 18,742, respectively), and the FDA's full-time, nonseasonal permanent employees make up less of its overall workforce—73 percent versus 89 percent at the EPA. The agencies have similar employee salaries, with FDA staff averaging a slightly lower \$103,473 compared to \$103,529 at the EPA. The FDA and the EPA are also unique among federal agencies in that a large proportion of their employees earn more than \$100,000 a year—56 percent at the FDA and 61 percent at the EPA.

The FDA has a larger proportion of temporary employees filling mission-critical occupations than the EPA, which may pose a challenge for the FDA in terms of institutional memory and succession planning. However, having a quarter (27 percent at FDA versus 11 percent at EPA) of its workforce composed of temporary employees could be an asset to the FDA as an employment pipeline. It gives the FDA an opportunity to assess talent that could be considered for permanent federal employment.

The FDA's reliance on temporary employees to fill mission-critical positions is significantly higher than at

the EPA. For example, 35 percent of the FDA's biologist positions are filled with term or temporary employees compared to 17 percent at the EPA, and 50 percent of the FDA's engineering positions are filled with term or temporary hires compared to 25 percent at the EPA. In addition, 68 percent of the FDA's statisticians are temporary employees compared to 36 percent at the EPA.

Age distribution of the total workforce at both the FDA and the EPA follow a general bell curve, with both agencies peaking in the three age ranges from 40 to 55. The FDA has a greater proportion of employees under the age of 40, which makes sense given that the FDA has a less federally experienced workforce overall in terms of years of service. The EPA has a slightly older workforce in all age groups over 40 years of age with the exception of the over-65 category. Consequently, the FDA has a larger standard deviation in age due to the considerably higher portion of employees under 25 and over 65 years of age.

Attrition at the EPA and the FDA

In fiscal 2010, 6.1 percent of all those employed at the EPA left the agency, compared to 7.2 percent at the FDA. Of the 6.1 percent, about 3 in 10 left the EPA because their temporary appointment expired, compared to more than 4 in 10 who left the FDA.

Fully 11 percent of those leaving the EPA did so to continue their civil service elsewhere in government, com-

pared with just 5 percent of those leaving the FDA. At the EPA, nearly 3 in 10 (28 percent) of those who left the agency resigned from the federal government altogether, and 27 percent did so to retire.

Overall workforce mission-critical attrition comparison

Our analysis shows that the FDA has far higher attrition rates among chemists, engineers and statisticians than the EPA. The EPA has slightly higher attrition rates among biologists, microbiologists, pharmacologists and toxicologists, and runs fairly similar to the FDA’s attrition rate among regulatory project managers and medical officers.

Attrition of mission-critical occupations at the FDA and comparable agencies

The table on page 33 shows the percent of mission-critical occupations from which employees left the FDA during fiscal 2010. The loss rate refers to the percentage of the workforce that left for any reason, including employees resigning and temporary employees who left because their appointment had run its course. Please note some of these losses are results of planned attrition, meaning attrition was the anticipated result of an appointment’s term expiration or retirement.

Compared to the same occupations at other scientific agencies, the FDA’s occupations with lower than average loss rates include biologists and toxicologists, while a relatively high loss rate is found for general engineers and statisticians.

Please see page 22 for the chart detailing the overall attrition of mission-critical occupations at the FDA and EPA.

FDA-EPA overall employee satisfaction comparison

Employees at the FDA were slightly less satisfied in the workplace than their counterparts at the EPA in 2011, based on the *Best Places to Work* scores of 66.9 and 67.9 out of 100 at each agency, respectively. Both agencies, as well as government overall, experienced a slight decline in employee satisfaction compared to 2010, but not as big a drop as one might have expected given the difficult economic and political climate that has led to a federal pay freeze, the possibility of reduced worker benefits, threats of government shutdowns and the certainty of significant agency budget reductions. Both agencies are slightly above the overall government-wide employee satisfaction score in 2011 of 64.0.

Some of the workplace issues in which the EPA is noticeably more satisfied than the FDA include performance-based rewards and advancement, support for diversity and pay.

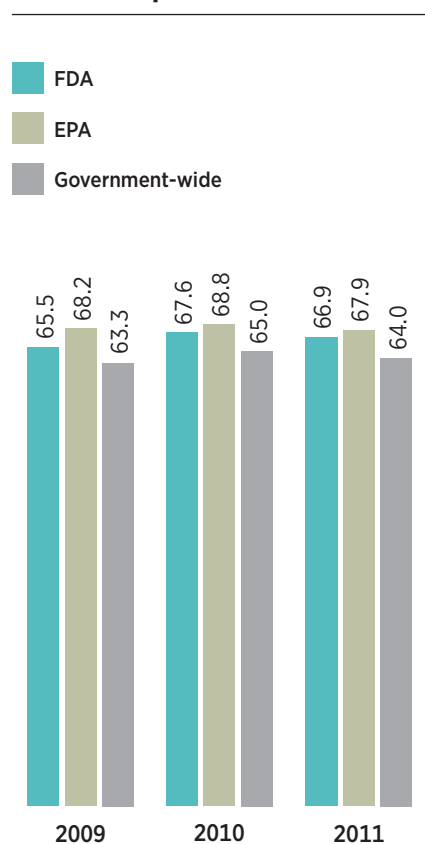
Perhaps the most impressive finding in employee satisfaction at the FDA in 2011 comes from the improvements it experienced in demographic scores and rankings. The agency improved its score in various categories of diversity by race, gender and age, with a 1.6 percent improvement among women and a 2.5 percent improvement among black employees. The EPA, however, has maintained higher diversity scores in the past two years compared to the FDA.

Both agencies continue to have fairly wide job satisfaction gaps between staff and managers. At the FDA, the category in which staff and managers most diverged was in work/life balance, with staff disagreeing more strongly than managers about having a reasonable workload and sufficient resources to get their job done. EPA staff, on the other hand, showed stronger dissatisfaction than managers regarding

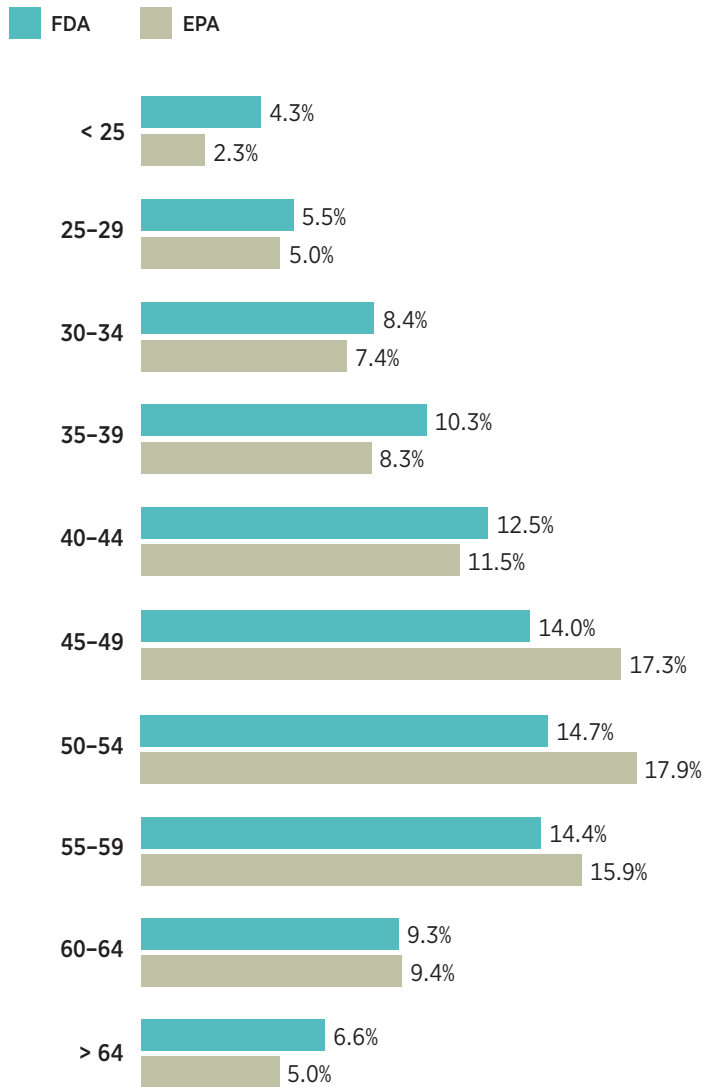
agency recruitment practices, effective leadership and performance-based rewards. In fact, the largest single gap reported pertained to the question of whether promotions at the EPA are based on merit in an employee’s work unit. On this question, the gap between staff and managers was 34.8 points.

Nonetheless, both the FDA and the EPA improved from 2010 to 2011 their staff-manager alignment scores, a *Best Places to Work* assessment that measures whether employees and managers see eye-to-eye on a range of workplace issues. But the FDA gets a much higher alignment rating than the EPA, indicating it is perhaps better positioned for change.

Best Places to Work index score comparison

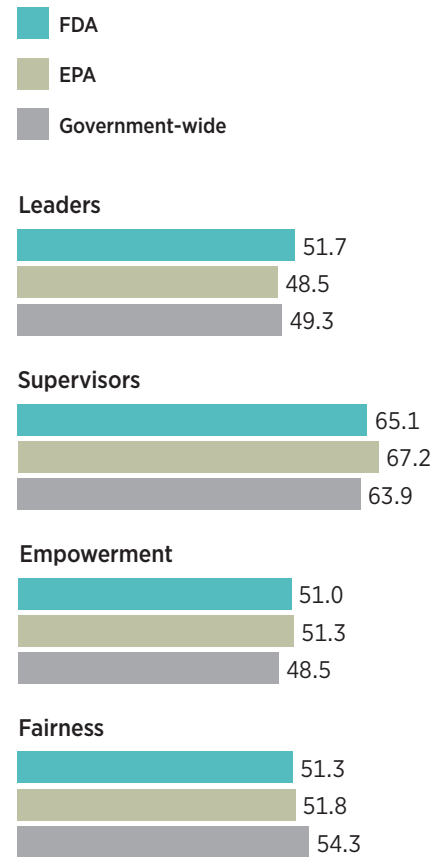


Age distribution of the total workforce at FDA and EPA



Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

2011 Best Places to Work scores in leadership sub-categories



Workforce profiles of FDA and EPA

	FDA	EPA
Total number of employees	14,824 (73 percent, or 10,826 employees, are categorized as full-time, nonseasonal permanent)	18,742 employees (88 percent, or 16,601 employees, are categorized as full-time, nonseasonal permanent)
Pay	The average employee makes \$103,529 a year. Fifty-six percent make over \$100,000 a year.	The average employee makes \$104,504 a year. Sixty-one percent make over \$100,000 a year.
Federal tenure	The average FDA employee has served in the federal government for 12 years. Twenty-eight percent have served less than 3 years in the federal government.	The average EPA employee has served in the federal government for 17 years. Thirteen percent have served less than 3 years in the federal government.
Retirement eligibility among permanent workforce	14 percent eligible to retire by fiscal 2010 22 percent eligible to retire by fiscal 2013 28 percent eligible to retire by fiscal 2015	18 percent eligible to retire by fiscal 2010 28 percent eligible to retire by fiscal 2013 36 percent eligible to retire by fiscal 2015

Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

Mission-critical occupations at FDA and at comparable agencies, fiscal 2010

	FDA			EPA			NIH			CDC		
	Total	% of workforce in occupation	% temporary	Total	% of workforce in occupation	% temporary	Total	% of workforce in occupation	Total	% of workforce in occupation	Total	% of workforce in occupation
Consumer safety officer	2,904	20	1	0	0	N/A	1	0	0	0	0	0
Medical officer	2,310	16	80	23	0	74	1,745	9	363	4	4	4
Chemist	1,105	7	13	578	3	13	563	3	185	2	2	2
Biologist	675	5	35	1,097	6	17	2,571	13	330	3	3	3
Microbiologist	629	4	16	107	1	28	409	2	477	5	5	5
General health scientist/ Regulatory project manager/ Epidemiologist	627	4	48	184	1	44	2,455	13	1,767	18	18	18
Pharmacologist	417	3	30	33	0	79	111	1	0	0	0	0
Mathematical statistician	296	2	31	34	0	35	100	1	119	1	1	1
Pharmacist	196	1	32	0	0	N/A	94	0	0	0	0	0
Biomedical engineer	194	1	45	2	0	50	39	0	7	0	0	0
Veterinary medical officer	116	1	30	18	0	89	75	0	22	0	0	0
Toxicologist	85	1	28	251	1	33	49	0	19	0	0	0
Operations research analyst	48	0	4	9	0	0	4	0	8	0	0	0
General engineer	42	0	50	57	0	25	49	0	76	1	1	1
Statistician	37	0	68	74	0	36	70	0	211	2	2	2
Other	5,143	35	17	16,275	87	10	11,100	57	6,154	63	63	63
TOTAL	14,824		27	18,742		22	19,435		9,738		9,738	

Source: Analysis of the Office of Personnel Management's Central Personnel Data File (EHRI-SDM)

A CASE STUDY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'S (CDRH) NEW TRAINING INITIATIVE

In its 2007 report, FDA Science and Mission at Risk, the Science Board's subcommittee on science and technology concluded that the Center for Devices and Radiological Health (CDRH) required more resources and personnel to better understand and support the science needs of emerging technologies, such as wireless devices, nanotechnology and robotics. The report's pull-no-punches review also made clear that, while more people and resources were necessary, these would not be sufficient. Without well-defined strategic priorities and viable plans to execute them, other material additions would serve only as a Band-Aid.

The CDRH leadership is seeking to meet this challenge. In 2010, the CDRH rolled out an aggressive three-year strategic plan built around a core set of priorities. The program aimed to develop and retain a capable and efficient STEM-focused workforce—one supported by a culture that values transparency and continuous learning. CDRH has been implementing the plan, has completed or launched many of the elements and is in the process of finalizing others.

There is one caveat. Although CDRH has been implementing its strategic plan, it's probably unrealistic to expect major impacts on CDRH's mission outcomes in a short time frame. At the same time, it is not too early to assess progress, to identify promising directions and to flag potential barriers to longer-term success of workforce and performance initiatives. In fact, mid-course re-

views can be very good ways to take stock and to make sense of how CDRH is doing and what the FDA's other centers may be able to learn from its experiences to date.

Background

CDRH was formed in 1982 as part of an FDA reorganization that merged the Bureau of Medical Devices with the Bureau of Radiological Health. The center's basic mission is to ensure that marketed medical devices are safe and effective, and to support innovation in the development of new and more effective medical devices.

CDRH regulates a wide variety of medical devices. These include diagnostic products, which range from complex CAT scanners to common laboratory tests, as well as therapeutic products, ranging from artificial hips and joints, to stents and topical cosmetic gels. CDRH's regulatory functions can be grouped into two main categories:

- **Pre-market activities**, which involve review and approval of new medical devices before they can be marketed and sold in the United States. CDRH sets requirements for device submissions and also provides guidance to industry on plans to test the effectiveness and safety of new products. CDRH interactions with industry may include input on study design, data gathering and analysis.

- **Post-market activities**, which involve the monitoring, manufacture and use of devices after they receive FDA approval. CDRH helps ensure that approved products meet performance and safety standards and remain in compliance with appropriate regulations throughout their life cycle. The center also gets involved in a range of activities, including notifications and recalls, if approved products later demonstrate adverse results.

Today, only a small percentage of all medical products require intensive pre-market review and testing by CDRH. The great majority of devices come to market under an expedited 510(k) approval process that allows a manufacturer to begin selling the product if it is judged “substantially equivalent” to an existing one. At the same time, tremendous and ongoing advances in science, technology and manufacturing have meant steady growth in the number and complexity of pre-market submissions that CDRH must be prepared to handle.

The center’s primary stakeholders include industry groups, which are seeking approval for new products or whose approved products CDRH monitors; the public, which uses or is affected by medical devices; and various consumer groups, which often provide third-party monitoring of medical devices and related products. Like many regulatory organizations, CDRH has been routinely criticized by both industry and consumer advocates. The former group has generally pushed to streamline and speed up the regulatory process—particularly in the pre-market phase—while the latter has often sought more checks on safety through tighter regulation of medical devices.

Assets and challenges

Successful change efforts typically begin with an accurate assessment, taking stock of an organization’s current state. This means not only identifying the key challenges it faces, but also recognizing the potential advantages it can harness to help move forward. A holistic assessment provides decision-makers with a clearer picture of what they have to work with, making it possible to develop strategic plans and approaches that are both appropriately focused and viable.

In its 2007 review of CDRH, the Science Board subcommittee went out of its way to highlight several key strengths of the center. The report credits CDRH with working “in earnest to carry out its scientific mission,”⁹ and then underscores this statement with three pages of mission-related examples that support it. Despite re-

maintaining shortcomings, the report recognized CDRH for making progress in improving its science infrastructure and management processes, and praises management’s motivation and efforts in responding to constructive criticisms and recommendations.¹⁰ Our own interviews found a staff dedicated to the center’s mission and their work.

At the same time, CDRH faces an array of challenges. These include resource constraints and heavy staff workload; difficulties recruiting and developing employees; deficits in emerging science and technology areas; inconsistencies and inefficiencies communicating with stakeholders externally and internally; and high attrition rates in core positions. Many of these challenges mirror those found across the FDA in its other centers. However, several key challenges also appear to be, if not unique to CDRH, at least more pronounced than those found elsewhere in the FDA, as well as more central to the CDRH’s strategic priorities for change.

Approach and priorities

While CDRH was unlikely to be pleased with the results of the 2007 report, the center has moved consistently to understand the “whys” behind key challenges and what can be done in both the short and long term to make progress. The steps have included: talking with internal staff; talking with industry representatives, consumer safety advocates, academic scientists and other stakeholders; establishing internal groups to gather and analyze additional data; and commissioning independent consultants to provide further perspective on CDRH’s challenges and path forward. Importantly, the results have been used to inform strategic priorities and to develop and implement action plans.

In short, rather than playing the “blame game,” CDRH ultimately took ownership of the critiques and went looking for answers. External challenges were certainly flagged, where appropriate, but CDRH began by looking inward for root causes. Dr. Jeffrey Shuren, an FDA veteran who became the center’s director in 2010, now heads these efforts. CDRH published its first annual strategic priorities summary report in 2010 and has issued follow-up reports in 2011 and 2012.

Strategic priorities

CDRH’s top four strategic priorities include: (1) taking responsibility for medical devices throughout the life cycle from approval to manufacture and use; (2) being clear with stakeholders about CDRH requirements and transparent about why they matter; (3) strengthening the center’s workforce and workplace; and (4) facilitating innovation around unmet public health needs. Regarding the

9 Food and Drug Administration, *Science and Mission Risk: Report of the Subcommittee on Science and Technology* (Washington, DC: GPO, 2007), Appendix H-1, H1-H4.

10 *Ibid.*, pp. H5-H6.

workforce, the priorities specifically involved developing staff skills and improving the center's work environment to more fully support accomplishing key mission requirements. This included proposals to recruit, develop and retain high-quality employees needed to execute on CDRH's mission; leveraging external expertise to expand breadth and depth of knowledge; developing processes and paths to resolve differences of opinion raised by external stakeholders; and improving internal administrative processes to facilitate efficiency.

From planning to action

A major initiative that came from the strategic planning and goal setting can be found in the CDRH's decision to overhaul the training for product reviewers—a mission-critical position in the center's pre-market review and approval of medical devices. Problems with the review process were well known and included:

- High workloads for reviewers and frequent delays in processing requests
- Spotty staff knowledge of the 510(k) review process, resulting in inconsistent decisions
- Inadequate supervision of reviewers
- Poor reviewer communication with industry submitters, particularly in clarifying review standards, expectations and the basis for CDRH decisions
- High reviewer attrition rates—double the rates found elsewhere at the FDA

A working group formed to address the problems. They found that the main causes stemmed from a lack of focus and clarity of expectations. Previously, training classes were “all over the map,” lacking a core curriculum that all reviewers completed. Because the classes were not mandatory, some busy reviewers stopped taking them—often on the advice of managers, who tended to prioritize immediate work over elective training. There was no strong incentive to do otherwise. The classroom training lacked a “field” component, making it harder for program trainees to fully appreciate the perspective of those submitting applications and going through the review process. Finally, the way electives were structured both increased the costs of training—due to the many offerings—and also limited opportunities for reviewers to interact, share knowledge and get to know each other as a cohort.

According to several CDRH directors and an administrator we spoke with at the Staff College—the center's training and development arm—the planning phase was thorough and inclusive, but not excessive.

CDRH set up a working group to incorporate multiple views, gathered input, developed and vetted an approach and then piloted it to “get the bugs out.” As one CDRH official observed, there is a tendency in government, and particularly in regulatory agencies, not to move until programs “are perfect and have been blessed by every director. This is not how we've approached it,” the official said.

Finally, one official noted that there is a prevailing concern among managers that any change requiring union involvement will take time. At CDRH, this concern can easily become self-fulfilling. Managers and directors simply don't pursue some initiatives because they believe it will take too much of their time to deal with the union. In contrast, the official attributed part of Shuren's success to his willingness to regularly work with union officials on key initiatives.

Implementation

Although “action planning” has become a jargon term in organizational development work, the basic concept is sensible and straightforward—that strategic priorities and plans should link to key goals and actions. The actions that organizations identify should be viable ones that they intend to take.

CDRH's priorities are closely connected to several overarching goals and to a set of specific actions and behaviors designed to help “move the needle.” However, these connections do not imply that priorities, actions and goals align on a one-to-one ratio. Reality is more complex. Achieving a single large goal, such as changing culture to improve collaboration, might require integrating multiple priorities and actions. Conversely, a key priority such as “strengthening the CDRH workforce” might spur multiple actions to improve staff training, which could then support a host of other CDRH priorities and goals. CDRH's current goals, subgoals and related actions are detailed in one of the center's reports.¹¹

CDRH's new reviewer training and certification program was rolled out in 2011 and incorporated elements to address each of the root causes identified by the working group. According to a senior official at the center, the program was designed around three basic tenets: (1) set clear expectations; (2) create a training roadmap for skills growth; and (3) provide needed oversight, support and mentorship to help reviewers make the most of the training opportunity. Specifically, the program:

- Has established a core curriculum for product reviewers. This ensures consistency of training and also allows CDRH to more efficiently allocate resources

¹¹ Center for Devices and Radiological Health, Medical Device Pre-Market Programs: An Overview of FDA Actions (Washington, DC: 2011).

to select course offerings. Core classes include: food and drug law; medical device law; 510(k) review of submissions; writing for regulators; risk communication; time management; and problem solving.

- Makes the curriculum mandatory for new reviewers. The mandatory requirement ensures that new reviewers and their managers understand the program's priority and take the classes. It is a two-semester program, which takes about 40 to 80 hours in total time over the course of a year.
- Provides graduates with an official certification and acknowledgement for completing the program. Certification has elevated perceived value of the program for reviewers.
- Increases interaction among new reviewers. Because new reviewers now take a series of classes together, they have a chance to interact more regularly and to build stronger connections. The hope is that these connections provide additional support and encourage knowledge-sharing.
- Uses knowledgeable CDRH staff as trainers/instructors for the program. CDRH taps its experts to teach new reviewers, both to provide top training and to open up additional communication channels. Reviewers get to know the experts and can find them later if they need help.
- Provides hands-on learning opportunities designed to take reviewers into the field to see manufacturing plants and places where devices are being used.

The first group of reviewers completed the program in 2011 and is continuing. Although we weren't able to interview program participants directly for this report, CDRH officials we spoke with said the initial reception has been very positive. One confided that the response from current participants has led a number of more seasoned reviewers to inquire about participating. Due to limited funding, however, seasoned reviewers are currently ineligible to enroll in the program.

Following on the initial success of the reviewer training program and using a similar process, CDRH's Staff College has designed a program for managers to address training and development issues. This program is centered on a core curriculum and is mandatory. Director Shuren's willingness to make the program mandatory for managers is critical to the program's viability, according to one official we spoke with. Without "teeth" in the program, many office directors would not allow their busy managers to attend.

Lessons learned

STEMM employees are hard to find and keep. CDRH officials acknowledge that they are never going to compete with industry on employee salaries. Yet, attrition remains a key concern for the center overall (9.7 percent annually among all CDRH employees, and 5.8 percent among permanent employees versus 4 percent for the FDA overall) and for key subgroups, including product reviewers and managers. At the same time, CDRH has several key strengths on which to draw. Employees are passionate about their work and their ability to have an impact on public health at a national level.

The center's leaders have been asking themselves a key question: "How do we create a workplace and an environment where people will want to come and stay?" The answer so far has been to tackle its people and performance issues together. In fact, a key insight emerging from the center's change efforts to date is that success on people issues and larger mission goals can go hand in hand. It's still early in the process and organizational change takes time. But anecdotal evidence suggests that CDRH is moving in the right direction.

The process for making changes at the center has generally followed these steps:

- Ensure that CDRH priorities are clear and communicate them to staff and other key stakeholders
- Connect priorities to goals and to specific actions designed to further those goals
- Use top priorities as a filter to help allocate the center's funding to key change initiatives
- Get the right people on the team to address particular change initiatives
- Seek input and incorporate multiple perspectives
- Vet the results but don't aim for "perfect"
- Use pilots and make changes as needed
- Communicate progress regularly to staff other key stakeholders

As the preceding steps suggest, CDRH understands that there is no silver bullet to change a culture. Rather, positive changes happen from a set of smaller steps that are ongoing and well coordinated. The center has openly acknowledged its many challenges and looked both inside and outside its walls for answers and solutions. It has also taken care to identify its core strengths—principally the dedication of its employees—and to ensure that any plans build on and reinforce these strengths.

To move from planning to "doing," CDRH has connected its plans to end goals through a set of defined

actions that make the center’s direction more concrete. And instead of keeping these plans under wraps, CDRH seeks to regularly communicate both the big picture and shorter-term detailed decisions as they happen to its employees and various stakeholders. At the same time, there is recognition among senior officials we spoke with that CDRH operates in a dynamic environment. The best laid plans may need to be tweaked or even scrapped as circumstances shift. The only way to learn what works is to start.

Finally, in order to follow this approach, CDRH needs champions in senior leadership who are willing to take risks. Based on comments of officials we spoke with, Director Shuren and several others are filling these roles. At the same time, “not all office directors are on board,” according to one official. Some are still “waiting in the wings to see what happens. Hopefully they will climb on board when they start to see more success,” the official said.

Ongoing challenges

CDRH continues to face a range of challenges. Although it has defined a strategic path forward and has been implementing a range of initiatives, it will take time—perhaps years on some initiatives—for the center and its stakeholders to experience the full effects. In addition, there are several cross-cutting challenges that have the potential to slow or limit progress on the center’s change efforts more generally. These include:

- **Maintaining balance between strategic and operational needs.** Despite recent progress and the emergence of key champions, CDRH it is still a tough place to sell strategic planning and to test new approaches. Immediate operational needs tend to trump strategy, in part, because the center’s “just do it” culture has traditionally promoted those managers able to prioritize and do the operational work. As one senior advisor we spoke with noted, “Just try telling a time-strapped office director that you need to take four or five of their best people to work on strategic planning issues for six months and see what kind of reaction you get.” Unless CDRH takes care to incentivize and recognize its managers’ strategic contributions, on par with operational ones, nascent change efforts are unlikely to garner the wider support they need to succeed long term.
- **Measuring progress in addition to desired outcomes.** CDRH can do more to translate its plans, programs and model for change into meaningful progress measures that can be tracked. When asked about metrics, one senior director noted that the center tracks employee attrition, time to fill vacant posi-

tions, and employee satisfaction questions from the Federal Employee Viewpoint Survey. While these metrics are all good ones, they tend to be high level and their effect might not be apparent in the short term.

In contrast, culture change is about building and sustaining momentum, which results from small behaviors happening regularly within an organization. Even for long-term goals, it is important to be able to document progress, share good news with stakeholders and help organizations stay the course. CDRH should develop progress measures that identify meaningful behavior changes resulting from its actions to improve training and development. These might include tracking changes in how industry customers regard the clarity of the center communications and the consistency of its guidance. In addition, pulse surveys might be used to gauge shifts in behavior of CDRH reviewers internally.

- **Protecting champions of change.** Culture change is a marathon, not a sprint. CDRH must help ensure that Shuren and other champions of the center’s change efforts can sustain their energy for the work to come. This is a critical but often overlooked concern. For senior officials, in particular, there is a continual need to make the case for support from congressional appropriators, industry, safety advocates and employees, as well as to lobby key groups for additional resources. This takes essential time away from implementing changes within the center and reinforcing desired culture shifts. The center needs to build a support structure to ensure that its key champions can stay engaged in guiding the actual work of change, not just advocating for it.

RECOMMENDATIONS

The FDA leadership needs to align its new responsibilities in the rapidly developing scientific world to its staffing competencies, giving top priority to ensuring the agency has the scientific expertise it needs. Based on our findings, we recommend that the FDA:

Improve the recruiting and hiring process

- **Develop targeted recruitment programs in high-priority scientific and medical disciplines.** This requires developing special recruitment programs, enhancing internship and fellowship opportunities, making better use of job fairs and developing meaningful long-term partnerships with academic institutions and the NIH to build pipelines for mission-critical talent.
- **Develop a systematic plan to recruit executive and scientific talent from outside the agency.** This can bring in individuals with management experience, fresh perspectives and new scientific expertise to the job. At the same time, FDA should seek to broaden the managerial experience of current executives by giving them rotating assignments within the FDA or in other agencies to enhance their capabilities.
- **Create a map of the current hiring process to guide needed changes.** As FDA seeks to improve its ability to attract and hire highly talented and motivated staff, it will be important that there be a clear understanding of the strengths and weaknesses of the current process and a blueprint for change. The “hiring toolkit” on the OPM website (<http://www.opm.gov/hiringtoolkit/>) is one useful reference to guide changes. While this approach is a best practice recommended by the Partnership for agencies across the government, we believe the FDA could benefit from conducting a thorough assessment of its hiring techniques.
- **Ensure that FDA subject matter experts are involved in defining the roles and responsibilities for STEMM jobs** and are meaningfully involved in the assessment of job applicants for critical STEMM leadership and project management positions. This will increase the odds of making the best job/person match.
- **Maximize use of FDA’s direct hire authority and the hiring flexibilities under Title 42.** These flexibilities, when used strategically, give FDA a definite advantage in its quest to hire top talent into mission-critical STEMM positions quickly and efficiently. Success will require a highly functioning HR system and staff, and substantive involvement of the FDA scientists and managers in the recruitment and hiring process.
- **Develop and track ways to measure the quality of new hires.** Metrics are crucial to ensuring the FDA is getting the best talent possible for mission-critical jobs. As part of a best practice we recommend for federal agencies, measures should include assessment of applicant and manager satisfaction data that focuses on timeliness and quality of applicants selected. The FDA should also track conversion to full-time employment of participants in fellowship and intern programs, as well as employees hired on a temporary basis.
- **Benchmark the best recruitment and hiring practices of each FDA center and create vehicles to encourage collaboration.** While looking outside of the FDA for ideas on how to improve hiring and re-

cruitment is useful, there is also much to be learned introspectively. Some FDA centers have developed approaches and strategies that can be beneficially transferred to other centers.

- **Make exit interviews mandatory and develop an approach that, to the maximum extent possible, ensures candid feedback is gathered.** Given the extensive amount of time and resources it takes to recruit and hire top STEMM employees, gathering feedback from departing employees in a consistent instead of a sporadic way across all centers can be useful in improving the hiring and onboarding processes.
- **Improve the FDA's external communications to the general public.** Fostering a better understanding of the FDA, what it does and who it hires and making its public health mission part of the recruitment process is imperative in order to attract people who care about protecting the health of their fellow citizens.

Update all workforce and human capital plans

- **Follow through on plans to update the FDA Strategic Human Capital Plan and Workforce Analysis Plan both agency-wide and for each FDA center.** This requires involving key FDA managers and executives, not just the HR staff, in the development of the plans. FDA managers also must “own” the plans and be held accountable for meeting goals and objectives. Care should be taken to ensure that the workforce plans touch on the entire employee “life cycle,” which includes recruiting, hiring, onboarding, developing, motivating and retaining a high-performance workforce.
- **Provide regular—and meaningful—reports to senior management on progress made or not made on key items.** It is unclear that progress toward meeting the specific performance measures in the current plans is being tracked and shared with top management in any meaningful fashion. Those plans should have objectives and performance measures focused specifically on the steps that will be taken to successfully operate under a decentralized HR operating model.
- **Clarify goals, outcome-focused performance measures (versus process-focused), target dates and identification of the individuals responsible and accountable for results in all strategic human capital plans developed by individual centers.** The center plans should be consistent with the overall goals and direction set by FDA headquarters, but they

should be even more targeted and outcome focused than the overall FDA plan. This would include specific recruitment and retention targets and measures.

- **Share successes and lessons learned regarding the development and implementation of an effective Human Capital Strategic Plan across centers.** Some centers are likely to have more success than others in developing actionable and effective human capital plans and workforce analyses. Regular sharing and collaboration among the centers in this regard should be actively encouraged.

Measure and track progress and hold agency leaders accountable

- **Include HR managers and those involved in restructuring the HR system in the gathering and updating of data and information that will help assess progress and identify any need for mid-course corrections in the workforce plans.** This should include, for example, data that identifies any competency gaps, progress made in closing those gaps and tracking the success of strategies for meeting new talent needs.
- **Hold agency leaders accountable for fully engaging their employees in the mission.** Maintaining high levels of overall employee job satisfaction and commitment will be as important as bringing in highly qualified employees in the first place. The results of the 2011 Federal Employee Viewpoint Survey and the associated 2011 *Best Places to Work in the Federal Government*[®] analyses will serve as a valuable benchmark for FDA's analysis of its 2012 employee survey findings and the forthcoming 2012 *Best Places to Work* update.
- **Assess the impact on agency performance of the relatively high number of temporary or term appointees filling mission-critical positions.** Tracking the mix of permanent and nonpermanent employees and the impact a particular combination is having over time will help achieve the optimal balance.

Continue to invest in career training and leadership development

- **Create better defined career paths for STEMM employees** to help them understand what they need to do to move up to the next level.

- **Develop a more robust strategy for leadership development within the FDA scientific community.** It has become almost axiomatic to note that the most talented scientists and technical experts do not always make the best leaders—at least not without help.
- **Support professional growth through training, as well as participation at professional conferences and scientific forums, and among the specific scientific professional communities to which these employees belong.** This support should come from the top down and be owned by every person at the managerial level.

Don't neglect retention and succession planning

- **Develop replacement strategies,** using temporary or term appointments, to ensure that a healthy pipeline of critical talent is available when needed.
- **Identify the staffing needs as well as tools and resources the staff needs** to increase agency performance effectiveness.
- **Take a closer look at occupations with higher attrition rates,** including pharmacists and consumer safety officers, and take measures to understand the causes and correct the problem.
- **Ensure succession plans are up to date** and that strategies exist for addressing key losses.

METHODOLOGY

The Partnership for Public Service was commissioned by the Pew Charitable Trusts to conduct background research on the hiring and staff retention methods of the Food and Drug Administration (FDA). We documented the FDA's recruitment practices and the attitudes of science, technology, engineering, mathematics and medicine (STEMM) employees who work in these mission-critical positions and assessed the FDA's retention challenges. We set out to better understand the agency's approaches and progress in these areas, and to explore opportunities for the agency to be even more effective.

Between November 2011 and January 2012, we conducted more than 30 interviews with a cross section of managers and directors from the Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Drug Evaluation and Research (CDER); Office of the Chief Scientist; Office of Regulatory Affairs (ORA), and with the HR staff in charge of hiring and evaluating STEMM employees at the FDA. The purpose of the approach was to understand how current FDA employees see progress or specific challenges to driving meaningful changes in the human capital process to achieve mission goals.

In addition, we held two discussion groups, one with academics and another with a broad network of industry officials, to assess their successes and challenges in hiring, developing and retaining STEMM employees, to gauge if some of the things they are doing may be of help to the FDA.

We performed a literature search; reviewed agency documents, congressional testimony and independent scientific papers; and did an in-depth review of the FDA's Strategic Human Capital Workforce Plan. We also conducted a quantitative analysis of government databases and data sets that addressed employee satisfaction, worker profiles and retention rates. The data for this report comes from three sources: FedScope, the Office of Personnel Management's Central Personnel Data File (EHRISDM) and the Federal Employment Viewpoint Survey. The numbers contained in the report are the most recent available, as of February 2012.

For the in-depth analysis of the CDRH training program, we conducted an additional set of targeted interviews with senior executives and directors, as well as several middle managers and first-line supervisors involved in the center's key learning and compliance initiatives. We also conducted a detailed analysis of CDRH's annual strategic priorities plans from 2010 to 2012, external assessments commissioned by CDRH and the center's own internal reports and recommendations on how to address key challenges.

The goal of this mixed methodology was to determine what in the FDA's staffing life cycle works, what doesn't work and why. This includes recruiting and hiring, onboarding, developing and retaining top STEMM talent, in order to recommend ways to make the FDA the world's most effective 21st-century workforce.



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