



January 2022

FDA WORKFORCE

Agency-Wide Workforce Planning Needed to Ensure Medical Product Staff Meet Current and Future Needs

Accessible Version

Why GAO Did This Study

FDA relies on a qualified medical product workforce to achieve its mission to protect public health. However, FDA has faced challenges meeting its medical product workforce needs, due in part to competition with the private sector for candidates.

Enacted in 2016, the 21st Century Cures Act provided additional flexibilities to facilitate FDA's recruitment and retention of medical product staff and included a provision for GAO to study FDA's recruitment and retention of these staff. This report: (1) describes the strategies FDA uses to recruit, hire, and retain medical product staff, and (2) evaluates the workforce planning processes FDA uses for these staff and whether these processes follow leading workforce planning practices.

GAO analyzed FDA policies, guidance, reports, and data related to recruitment and retention of medical product staff and workforce planning. GAO also interviewed FDA officials responsible for hiring these staff and nonprofit and private sector organizations representing scientific staff.

What GAO Recommends

GAO is recommending that FDA (1) develop and implement an agency-wide strategic workforce plan with performance measures to ensure it can evaluate the effectiveness of its human capital efforts and (2) establish an ongoing process to update this plan. We provided a draft of this report to HHS for review and comment. HHS concurred with our recommendations.

View [GAO-22-104791](#). For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

FDA WORKFORCE

Agency-Wide Workforce Planning Needed to Ensure Medical Product Staff Meet Current and Future Needs

What GAO Found

The U.S. Food and Drug Administration (FDA)—an agency of the Department of Health and Human Services (HHS)—is responsible for, among other things, ensuring the safety, efficacy, and security of human medical products marketed in the United States. FDA has used a variety of strategies to improve the agency's ability to recruit and retain the scientific, technical, and professional staff for its three centers responsible for the oversight of human medical products. These centers—the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health—were the focus of GAO's review.

To improve both recruitment and retention for these centers, FDA leveraged the hiring and pay flexibilities provided by the 21st Century Cures Act (Cures Act) to expedite hiring and to offer higher salaries than the agency could under traditional federal hiring authorities. FDA has used these flexibilities to hire and retain staff such as scientists, physicians, and regulatory counsel, for whom pay disparities with the private sector are especially large. FDA also established a team dedicated to engaging with the scientific community and established a unified branding strategy that emphasizes the agency's public health mission.

GAO found that FDA follows some leading practices for effective workforce planning for medical product staff. FDA's medical product centers each conduct yearly workforce planning in which they determine the skills they need and develop strategies to address identified gaps. However, FDA does not have an agency-wide strategic workforce plan to coordinate human capital efforts across the medical product centers, nor does it have performance measures in place to evaluate the effectiveness of its human capital strategies, as called for by leading practices of effective workforce planning.

FDA Workforce Planning Activities for Medical Product Staff As Compared to GAO-Identified Leading Practices for Effective Workforce Planning

Leading practice	Alignment between FDA actions and leading practices
Determine needed skills and develop strategies to address gaps	Aligned
Monitor and evaluate progress toward human capital goals	Partially aligned
Develop a strategic workforce plan	Not aligned

Legend: ● = Aligned with leading practices; ◐ = Partially aligned with leading practices; ○ = Not aligned with leading practices

Source: GAO analysis of Food and Drug Administration documents and interviews with officials. | GAO-22-104791

Further, FDA does not have a process to update such a plan on an ongoing basis should one be developed. FDA's last agency-wide strategic workforce plan—covering fiscal years 2010 through 2012—was developed under prior leadership and current agency officials were not aware of it. Without an agency-wide strategic workforce plan and a process to keep it up to date, FDA lacks reasonable assurance that actions taken within its individual centers and offices will help the agency achieve its overarching goals and mission over time.

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Abbreviations

CDER	Center for Drug Evaluation and Research
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
FDA	Food and Drug Administration
GS	General Schedule
HHS	Department of Health and Human Services
OHCM	Office of Human Capital Management
OPM	Office of Personnel Management
OTS	Office of Talent Solutions

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January 14, 2022

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Frank Pallone
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Food and Drug Administration (FDA), an agency of the Department of Health and Human Services (HHS), is responsible for protecting public health by, among other things, ensuring the safety, efficacy, and security of human medical products marketed in the United States.¹ To achieve this mission, FDA relies on qualified scientific, technical, and professional staff—such as physicians, scientists, and mathematicians—to conduct important oversight activities. For example, these staff (which we refer to throughout this report as medical product staff) are responsible for reviewing data and information to ensure that new medical products are safe and effective, inspecting establishments that produce medical products to ensure their manufacturing processes meet quality standards, and monitoring the safety of approved medical products over time.

FDA has historically faced challenges in recruiting and retaining sufficient medical product staff to meet its needs. Medical product staff are in high demand in both the public and private sector due to their technical skillsets, putting FDA at risk of losing these staff and making it difficult to fill vacancies, especially those in supervisory positions. In 2007, an

¹Human medical products include drugs, biological products, and medical devices. Drugs are chemically synthesized, while biological products—which include vaccines, blood products, and proteins, among other things—are derived from living sources such as humans, animals, and microorganisms. Medical devices include instruments, apparatuses, machines, and implants that are intended for use to diagnose, cure, treat, or prevent disease, or to affect the structure or any function of the body.

internal working group at FDA found that the turnover rate for FDA staff in key scientific areas was twice that of other government agencies, which partly contributed to the working group's conclusion that "the FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability." We found a similar challenge in 2010, when we reported that about 70 percent of FDA's career employees on board as of fiscal year 2008 would be eligible to retire by the end of fiscal year 2014.² Additionally, FDA reported in 2018 that 10 mission-critical occupations—primarily medical product staff—had salaries that were at least 20 percent lower than the average private sector salary for the same occupations. The agency said that supervisory positions in these fields are particularly challenging to fill because the agency is not able to pay enough to make it attractive for these staff to take on managerial responsibilities.³

We have designated strategic human capital management as a government-wide high-risk area in part because of the need to address current and emerging skills gaps that undermine agencies' abilities to achieve their missions.⁴ We have previously found that agencies across the federal government have struggled to identify skill gaps and the future needs of their scientific and technical staff, pay these staff salaries comparable to those of the private sector, and—because of limitations on conference participation—provide their scientific staff opportunities to engage with the broader scientific community.⁵ Additionally, regarding FDA specifically, the Partnership for Public Service in 2012 found that it can take between one and three years for FDA to get newly hired

²GAO, *Human Capital: Continued Opportunities Exist for FDA and OPM to Improve Oversight of Recruitment, Relocation, and Retention Incentives*, [GAO-10-226](#) (Washington, D.C.: Jan. 22, 2010).

³U.S. Food and Drug Administration, *FDA 21st Century Cures Workforce Planning Report to Congress*. (June 2018).

⁴Strategic human capital management refers to the talent management activities that agencies conduct to address skills gaps, such as robust workforce planning and training. See GAO, *High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas*, [GAO-21-119SP](#) (Washington, D.C.: March 2, 2021).

⁵GAO, *Science and Technology: Strengthening and Sustaining the Federal Science and Technology Workforce*, [GAO-21-461T](#) (Washington, D.C.: March 17, 2021).

scientific, technical, and professional talent up to speed on their jobs, which is of concern if there is high turnover among these positions.⁶

In December 2016, Congress passed, and the President signed into law, the 21st Century Cures Act (“Cures Act”), which, among other things, provides additional hiring and pay flexibilities to HHS to facilitate FDA’s recruitment and retention of medical product staff.⁷ These flexibilities allow expanded opportunities to directly appoint qualified medical product staff (which reduces the time it takes to hire new employees), and the ability for FDA to establish an alternative pay system to increase pay for medical product staff.

The Cures Act also included a provision for GAO to examine and report on FDA’s ability to hire, train, and retain qualified medical product staff necessary to fulfill its mission. In this report, we examine

1. strategies FDA uses to recruit, hire, and retain staff to meet its medical product workforce needs; and
2. workforce planning processes FDA uses for medical product staff, as well as whether these processes follow leading practices for workforce planning.

For both objectives, we reviewed policies, guidance, memoranda, and other documents from FDA on recruitment, hiring, retention, and workforce planning practices. This review focused on the three centers within FDA responsible for the oversight of human medical products—the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Center for Drug Evaluation and Research (CDER).⁸ We interviewed officials from these three centers as well as from the Office of Regulatory Affairs and from the two offices within FDA that focus on human capital issues—the Office of Talent Solutions and the Office of Human Capital Management. We also

⁶See Partnership for Public Service, *The State of the FDA Workforce* (Washington, D.C.: November 2012).

⁷Pub. L. No. 114-255, § 3072(a), 130 Stat. 1033, 1134 (adding Food Drug and Cosmetic Act § 714A, codified at 21 U.S.C. § 379d-3a).

⁸Throughout this report, we will refer to these three centers as “the three medical product centers.” We also interviewed officials from the Office of Regulatory Affairs because it has consumer safety officers who conduct field inspections and sampling of medical products as well as food products. However, because the office is not exclusively focused on medical products, it was not a primary focus of our study.

conducted interviews with officials from the Office of Personnel Management (OPM)—the primary entity responsible for human capital management across the federal government—and representatives from seven professional organizations for scientific staff in medical product occupations, human resource professionals, or the pharmaceutical industry.⁹ We chose these seven professional organizations to gain insight into how FDA interacts with the scientific community and how scientific staff may view FDA as an employer.

To further examine strategies FDA uses to recruit, hire, and retain staff, we reviewed FDA reports and presentations of workforce trends, including data on hiring, attrition, and pay, among other things. We assessed the reliability of the data through discussions with FDA officials and by reviewing relevant data documentation. We determined this data was sufficiently reliable for the purposes of our reporting objectives.

To further examine FDA workforce planning processes for medical product staff, we reviewed prior GAO reports outlining leading practices for workforce planning in the federal government.¹⁰ Specifically, we examined whether FDA’s workforce planning actions followed three leading practices identified in our prior work, including that agencies should: 1) determine needed skills and competencies and develop strategies to address gaps; 2) monitor their progress toward human capital goals and assess the effectiveness of human capital strategies; and 3) develop strategic workforce plans to coordinate human capital activities and align them with agency-wide goals.

We conducted this performance audit from February 2021 to January 2022 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe

⁹Of these seven organizations, three represented scientific staff in medical product occupations, three represented human resource professionals, and one represented the pharmaceutical industry.

¹⁰See GAO, *Human Capital: Key Principles for Effective Workforce Planning*, [GAO-04-39](#) (Washington, D.C.: Dec. 11, 2003); GAO, *Human Capital: Strategies to Help Agencies Meet Their Missions in an Era of Highly Constrained Resources*, [GAO-14-168](#) (Washington, D.C.: May 7, 2014); and GAO, *Federal Workforce: Key Talent Management Strategies for Agencies to Better Meet Their Missions*, [GAO-19-181](#) (Washington, D.C.: Mar. 28, 2019).

that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

FDA is responsible for ensuring the efficacy and safety of medical products marketed in the United States—including human and veterinary prescription drugs, biological products, and medical devices—as well as ensuring the safety of food products, products that emit radiation, and cosmetics, and reducing death and disease associated with tobacco products. To conduct its work, FDA relies on a workforce of over 18,000 individuals who are employed by 16 centers and offices under the Office of the Commissioner. The agency reported that in fiscal year 2020, more than half of its total workforce worked in one of 14 mission-critical occupations, many of which involve scientific, technical, and professional skillsets commonly used by medical product staff.¹¹ In addition, over 45 percent of the agency’s workforce in fiscal year 2020 were employed by the three medical product centers—CBER, CDRH, and CDER.

Title 5 of the U.S. Code includes a set of personnel provisions that apply to much of the federal government’s civil service system.¹² Most of FDA’s workforce is hired under the authority provided by these provisions, which we refer to as “traditional hiring.” Traditional hiring generally uses a process known as “competitive examining,” which requires agencies to: notify the public on the USAJOBS website that the government will accept applications for a job; screen applications against minimum qualification standards; apply selection priorities such as veterans’ preference, where applicable; and assess applicants’ relative competencies or knowledge, skills, and abilities against job-related criteria to identify the most qualified

¹¹These 14 positions include biologists, microbiologists, pharmacologists, toxicologists, medical officers, pharmacists, consumer safety officers, veterinary medical officers, biomedical engineers, chemists, operations research analysts, mathematical statisticians, criminal investigators, and information technology specialists. As previously mentioned, mission-critical occupations not focused on human medical products (or staff in mission-critical occupations who work on animal or food products, for example) are not the focus of our review.

¹²Title 5 includes, among other things, personnel management laws, procedures, and associated functions generally applicable to federal employees. Federal personnel laws governing topics such as classification, appointment, pay and benefits, and adverse action are contained in sections of Title 5.

applicants.¹³ Within the traditional hiring authority, FDA can use what is referred to as direct hire authority to fill vacancies under certain circumstances, such as for a critical hiring need.¹⁴ Direct hire authority expedites the traditional hiring process by eliminating competitive rating and ranking procedures and veterans' preference.¹⁵

Individuals hired under traditional hiring are typically covered by the General Schedule (GS) classification system—the federal government's system for defining and organizing federal positions, primarily to assign rates of pay based on a series of grades that reflect the complexity of the work and knowledge required to do the job.¹⁶ OPM establishes the basic policies, criteria, and guidance to classify occupations and grade jobs on the GS system. Agencies are required to place each of their GS positions in the appropriate class and grade, consistent with OPM's classification standards.¹⁷

In addition to traditional hiring, FDA reported using eight other hiring authorities for medical product staff. Many of these other authorities are limited to specific groups of personnel, and they provide the agency additional flexibilities in hiring, such as setting higher pay or using alternative standards instead of OPM classification standards. As of

¹³The USAJOBS website, which is managed by OPM, is the primary source for information about federal jobs and employment opportunities. It provides interested citizens with information on federal job opportunities and allows them to submit applications for these jobs.

¹⁴Congress authorized the delegation of authority to OPM to permit agencies to use direct hire authority for a position or group of positions where OPM has determined that there is either a severe shortage of candidates or a critical hiring need for such positions. 5 U.S.C. § 3304(a)(3).

¹⁵Agencies must comply with public notice requirements with respect to any position an agency seeks to fill using direct-hire authority. 5 U.S.C. § 3304(a)(3)(A); 5 C.F.R. § 337.203 (2021).

¹⁶The GS classification system was established by the Classification Act of 1949 (Pub. L. No. 81-429, 63 Stat. 954 (Oct. 28, 1949)). OPM, which is responsible for administering and overseeing the GS classification system, organized the work of the government into occupational groups and series and 15 grades (on a scale of GS-1 to GS-15). These grades determine an employee's rate of basic pay. Federal employees who are not white-collar workers are not covered by the GS system but are instead covered by the Federal Wage System, which is a uniform pay-setting system covering federal blue-collar employees. These employees are paid a prevailing wage comparable to private sector rates in each local wage area.

¹⁷5 U.S.C. § 5107.

October 2021, according to FDA, 80 percent of its employees were employed under traditional hiring and 20 percent were employed under other hiring authorities. Such other authorities include the newest one available to FDA, namely the hiring and pay flexibilities provided under the Cures Act to facilitate the hiring of scientific, technical, and professional personnel to support the development, review, and regulation of medical products.¹⁸ As of October 2021, according to FDA, approximately 6 percent of its workforce was employed under the Cures Act authority (see table 1).

Table 1: Hiring and Pay Authorities FDA Uses for Medical Product Staff, as of October 2021

Description of authority	Percent of FDA workforce employed under the authority	Applies to	Pay ranges (U.S. dollars)
Traditional hiring (Title 5) ^a	80	Most civilian federal employees under the GS classification system	Up to 170,800
Cures Act hiring and pay flexibilities ^b	6	Scientific, technical, and professional positions that support the development, review, and regulation of medical products	Up to 400,000
Public Health Service Commissioned Corps ^c	5	Uniformed service of the U.S. Public Health Service	Up to 328,484
Service/Staff Fellows ^d	4	Promising research and regulatory scientists	Up to 170,800
Physician and Dentist pay ^e	3	Physicians and dentists	Up to 400,000
Senior Science Managers/Advisors ^f	<1	Staff in non-executive positions whose duties are broad and complex enough to be classified above the General Schedule (GS)-15 level but are not eligible for the Senior Executive Service ^g	Up to 400,000
Senior Executive Service ^g	<1	Executive positions, including managerial, supervisory, and policy positions classified above GS-15	Up to 199,300
Senior Biomedical Research and Biomedical Product Assessment Service ^h	<1	Scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment	Up to 400,000
Senior Level Scientific Professional ⁱ	<1	Non-executive positions classified above the GS-15 level and that involve high-level research and development in the physical, biological, medical, or engineering sciences, or a closely related field	Up to 183,300

Legend: <1 = Less than one percent.

Source: GAO analysis of documentation from Food and Drug Administration (FDA). | GAO-22-104791

^a5 U.S.C. ch. 31, subch. I. "Traditional hiring" refers to those hired under Title 5 of the U.S. Code, a set of personnel provisions that apply to much of the federal government's civil service system. Individuals hired under traditional hiring are typically covered by the General Schedule (GS)

¹⁸Pub. L. No. 114-255, § 3072(a), 130 Stat. at 1134.

classification system—the federal government’s system for defining and organizing federal positions, primarily to assign rates of pay.

^b21 U.S.C. § 379d-3a. “Cures Act” refers to the 21st Century Cures Act, a law enacted in 2016 which, among other things, provided additional hiring and pay flexibilities to HHS to facilitate FDA’s recruitment and retention of medical product staff.

^c42 U.S.C. § 210.

^d42 U.S.C. § 209(g). These are temporary fellowship positions for research and regulatory scientists.

^e38 U.S.C. § 7431. Physicians and dentists under this pay band are hired under traditional hiring (Title 5), but they are paid under a different authority—Title 38. The Office of Personnel Management delegated to the Department of Health and Human Services (HHS) certain title 38 personnel authorities for health care occupations, including this authority, to use on a discretionary basis. See 5 U.S.C. §§ 1104, 5371.

^f42 U.S.C. § 209(f).

^g5 U.S.C. ch. 31, subch. II. The Senior Executive Service consists of federal executives selected for their leadership qualifications who serve in key positions within agencies, just below the top presidential appointees, and oversee nearly every government activity in approximately 75 federal agencies.

^h42 U.S.C. § 237.

ⁱ5 U.S.C. §§ 1104, 3104, 3324, 3325, 5108, and 5376.

The Cures Act hiring and pay flexibilities allow FDA to use additional processes and incentives to help it recruit, hire, and retain medical product staff. As shown in table 2, the Cures Act hiring process differs from traditional hiring in a number of ways, such as the number of steps required to hire staff.

Table 2: Traditional Hiring Authority Process Compared to the FDA Hiring Process Authorized through the Cures Act

Process component	Traditional hiring ^a	Cures Act ^b
Limitations on applicable positions	None	Positions must directly support the development, review, and regulation of medical products
Public notification of position on USAJOBS ^c	Required	Not required
Job descriptions	Standard descriptions based on OPM classifications	Created by agency based on needs of position
Application process	Must accept applications through public job posting	Simplified application process; can directly recruit and appoint candidates, with an option to advertise
Veterans’ preference	Required	Not required
Review of qualifications	Agency must use the standard competitive rating process to assess experience, education, and training and place candidates into pre-defined “quality categories”	Agency must document that candidate is “outstanding and qualified,” based on qualifications, work experience, or both

Source: GAO analysis of documentation from Food and Drug Administration (FDA). | GAO-22-104791

^a5 U.S.C. ch. 31, subch. I. “Traditional hiring” refers to those hired under Title 5 of the U.S. Code, a set of personnel provisions that apply to much of the federal government’s civil service system. In this table, “traditional hiring” does not include those hired under the Senior Executive Service nor those hired under direct hiring authority.

^b21 U.S.C. § 379d-3a. “Cures Act” refers to the 21st Century Cures Act, a law enacted in 2016 which, among other things, provided additional hiring and pay flexibilities to HHS to facilitate FDA’s recruitment and retention of medical product staff.

^cThe USAJOBS website, which is managed by the Office of Personnel Management, is the primary source for information about federal jobs and employment opportunities.

In addition, Cures Act pay flexibilities provide for higher pay ranges for medical product staff than what is available under the traditional hiring process. (See table 3.) For example, as of January 2021, the maximum annual pay for non-executive staff hired under the Cures Act was almost 37 percent higher than the maximum under traditional hiring. Similarly, the maximum annual pay for executive staff hired under the Cures Act ranged from 44 to 101 percent higher than the maximum under traditional hiring, depending on the Cures Act pay band.¹⁹ The Cures Act flexibilities can be used for both new hires to FDA and to convert or reappoint existing FDA staff. However, Cures Act flexibilities can only be applied to medical product staff, so centers and offices within FDA are unable to use these flexibilities if their scientific, technical, and professional staff do not support the development, review, and regulation of medical products.²⁰ Additionally, for many upper-level pay bands within the Cures Act pay structure, salaries above the midpoint of the pay band require agency approval.²¹

¹⁹Employees hired under the Cures Act are paid based on a series of three pay tables (based on the type of position) and up to nine pay bands (designated by letters A through I) within each table. The first six pay bands (A through F) are used for non-executives and, in general, allow for higher salaries than could be paid under the GS pay ranges. The three highest pay bands (G through I) are used for executives and senior level equivalents and, in general, allow for higher salaries than could be paid under the traditional Senior Executive Service pay ranges.

²⁰Other centers and offices outside of the medical product centers may be eligible to use Cures Act hiring and pay flexibilities, but only if they support the development, review, and regulation of medical products and only for certain staff who work in that capacity. For example, according to FDA, centers and offices that work exclusively on food or tobacco products are not eligible to use Cures Act hiring and pay flexibilities.

²¹Specifically, for Cures Act pay bands E through H, salaries above the midpoint require approval from the Cures Compensation Review Board, a group within FDA that oversees Cures Act hiring and pay policy and actions. All salaries within pay band I require approval from the FDA Commissioner.

Table 3: Examples of Pay Ranges for Medical Product Staff under Traditional Hiring Pay Scale Compared to Cures Act Pay Bands for the Washington, D.C., Region Non-Executive and Executive Staff, as of January 2021

U.S. Dollars

Type of staff and pay band	Minimum annual pay	Cures Act pay band midpoint ^a	Maximum annual pay
Non-executive staff: Traditional hiring (General Schedule (GS-15)) ^b	144,128	n/a	172,500
Non-executive staff: Cures Act (Pay Band F) ^c	163,962	199,758	235,553
Executive staff: Traditional hiring (Senior Executive Service) ^d	132,522	n/a	199,300
Executive staff: Cures Act (Pay Band G) ^e	199,213	242,987	286,760
Executive staff: Cures Act (Pay Band H) ^e	242,044	295,127	348,209
Executive staff: Cures Act (Pay Band I) ^e	281,640	340,820	400,000

Legend: — = Not applicable.

Source: GAO analysis of documentation from Food and Drug Administration and from the Office of Personnel Management. | GAO-22-104791

Note: Employees hired under the Cures Act are paid based on a series of three pay tables (based on the type of position) and up to nine pay bands (designated by letters A through I) within each table. The first six pay bands (A through F) are used for non-executives and, in general, allow for higher salaries than could be paid under the GS pay ranges. The three highest pay bands (G through I) are used for executives and senior level equivalents and, in general, allow for higher salaries than could be paid under the traditional Senior Executive Service pay ranges.

^aFor Cures Act pay bands E through H, salaries above the midpoint require approval from the Cures Compensation Review Board, a group within FDA that oversees Cures Act hiring and pay policy and actions. All salaries within pay band I require approval from the FDA Commissioner.

^b5 U.S.C. ch. 31, subch. I. "Traditional hiring" refers to those hired under Title 5 of the U.S. Code. The GS-15 pay grade is the highest non-executive pay grade under traditional hiring.

^c21 U.S.C. § 379d-3a. "Cures Act" refers to the 21st Century Cures Act, a law enacted in 2016. Pay Band F is the highest non-executive pay band under the Cures Act. Pay ranges align with those within Cures Act pay band F on Cures Act Pay Table 1, which are standard Cures Act pay bands.

^d5 U.S.C. ch. 31, subch. II. The Senior Executive Service typically serves in key positions within agencies, just below the top presidential appointees. These figures reflect base salary ranges for these personnel in agencies with Senior Executive Service-certified performance plans.

^eThe pay ranges align with those within Cures Act pay band G, H, or I on Cures Act Pay Table 1, which are standard Cures Act pay bands.

Following the enactment of the Cures Act, FDA established new agency-level governance boards and internal controls related to hiring, which were designed to help the agency implement the Cures Act flexibilities within its broader hiring framework. They include the following.

- **Cures Act Steering Committee:** This committee oversaw the initial implementation of the Cures Act authority, including developing the alternative pay structure and eligibility criteria for Cures Act flexibilities, and producing guidelines for consistent and proper use of the flexibilities across the agency. This committee's work was transferred to the Cures Compensation Review Board in December 2018.

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- **FDA Cures Compensation Review Board:** This board oversees Cures Act hiring and pay policy and actions. The board is responsible for establishing policy and approving policy changes for the Cures Act flexibilities for both executive and non-executive staff and for reviewing and approving Cures Act salaries for appointments within certain pay bands above a certain level. When salaries come to the board for review, each proposal includes compensation analysis that considers external market conditions for that occupation.
 - **FDA Performance Review Board:** This board oversees performance management and performance-based pay specifically for executives in four hiring authorities, including Senior Executive Service, Senior Level Scientific Professional, Senior Level Title 42, and Executive Cures Act positions.

FDA Has Used Various Strategies to Meet Medical Product Workforce Needs

FDA Reorganized Its Human Capital Offices and Established a New Team Dedicated to Scientific Recruitment

FDA reorganized its Office of Human Resources in 2018 into two separate, specialized offices to provide dedicated expertise and improved processes for recruitment and hiring. FDA officials from all three medical product centers said that this reorganization has improved recruitment and hiring efforts, specifically noting that it has resulted in more dedicated leadership for hiring and improved communication with the centers.

Office of Human Capital Management (OHCM). OHCM focuses on management of current employees and the employee experience, including onboarding new employees and managing employee performance and professional development. This office also develops programs to encourage employee retention such as campus events, professional development opportunities, and child care benefits.

Office of Talent Solutions (OTS) and the Scientific Staffing Outreach Branch. OTS leads the agency's recruiting, hiring, and personnel policy efforts and works with centers and offices across FDA to develop strategies for meeting hiring needs. This office also provides training and information to employees to help them implement new hiring authorities. To further improve recruitment of medical product staff, FDA also formally

established the Scientific Staffing Outreach Branch (hereafter referred to as the Outreach Branch) in 2018, which is dedicated to engaging with and recruiting from the scientific community. The Outreach Branch is led by a scientist and subject matter expert and has forged over 200 strategic partnerships with government agencies, professional associations, and academic institutions, according to FDA documentation and OTS officials.

The Outreach Branch took steps to improve recruitment by creating a unified branding and outreach strategy for the agency, according to officials from CDER and OTS. For example, the Outreach Branch developed an advertising campaign with ads that portray the agency as a place to “make a difference” serving public health. (See fig. 1.)

Figure 1: Example of FDA Recruiting Advertisement



Source: Food and Drug Administration (FDA) website, accessed on September 28, 2021 from <https://www.fda.gov/about-fda/jobs-and-training-fda>. | GAO-22-104791

Officials from all three medical product centers as well as OTS noted that the Outreach Branch’s work has improved FDA’s outreach to external organizations and prospective job applicants. Its work has expanded the agency’s social media presence, increased targeted advertising and messaging to job boards, established relationships with professional organizations for medical product staff, and created a centralized webpage for job postings. Representatives from two professional organizations for medical product staff occupations told us that FDA regularly engages with them through meetings and has been posting job announcements on industry job boards (see text box). This approach of forming strategic partnerships and developing a mission oriented recruitment strategy is consistent with leading practices agencies should use in their recruitment efforts, according to the Partnership for Public Service. Forming such relationships establishes a pipeline for talent and allows FDA to move beyond what stakeholders referred to as the “post and pray” approach, in which an employer posts a job with the hope that

the qualified candidates will apply, without conducting additional recruitment efforts.

Using FDA's Public Health Mission to Attract Employees

Representatives from professional organizations for scientific staff in medical product occupations characterized FDA as having a reputation among their members as a desirable place to work because of its mission and professional opportunities. For example, representatives from one organization for staff in medical product occupations told us that their members say that FDA's mission to protect public health is clear and is a draw for potential employees.

Source: GAO interviews with representatives from professional organizations for scientific staff in medical product occupations.

CDER officials also noted that working with the Outreach Branch on recruitment efforts has resulted in improved coordination among FDA centers. For example, they stated that, before the Outreach Branch was created, FDA centers might have participated at the same conference but worked independently of each other at that conference. Now, according to officials, all centers at conferences are represented as a unified, coordinated FDA presence.

FDA Has Implemented New Cures Act Flexibilities to Hire and Retain Staff

While FDA uses nine different authorities to hire staff, all three medical product centers in our review reported using Cures Act hiring and pay flexibilities to aid in hiring and retaining medical product staff. FDA officials said that they favor using the Cures Act flexibilities over traditional hiring because the flexibilities allow their centers to better target potential candidates and pay higher salaries both to external candidates FDA seeks to hire and to internal employees it seeks to retain.

Targeting Potential Candidates. Because Cures Act hiring does not require the agency to advertise for eligible positions on USAJOBS, it effectively acts as a direct hire authority, according to FDA officials. This allows the agency to directly target candidates who were already identified through recruiting efforts, including those candidates with qualifications needed to meet changing agency needs as industries develop new technologies and scientific fields change. For example, FDA officials told us they have used Cures Act hiring flexibilities to hire senior technical leaders in emerging scientific fields such as data science, information technology systems, and pharmaceutical science.

FDA also uses Cures Act flexibilities to add specificity to its job descriptions beyond what OPM classification standards can accommodate, according to FDA officials. As a result, FDA can tailor hiring to staffing needs that may not be covered in the existing OPM position descriptions and grading criteria, which may be outdated for some positions.²² For example, according to OTS officials, pharmacologist positions have been difficult to fill and retain due to outdated standards. Under traditional hiring, the pharmacology positions require a specific number of educational credits in chemistry, whereas today's pharmacologists might be highly qualified based on their PhD research but did not take enough chemistry credits as an undergraduate to be considered qualified by these standards. OTS officials told us the agency is more interested in hiring pharmacologists with experience than those with specific and prescriptive academic coursework.

In addition, representatives from a professional organization for pharmacologists stated that FDA job descriptions have not kept up with academic training at universities, as schools are advancing their curricula to incorporate new skills such as data science. While these are skills that FDA needs, FDA officials told us that traditional job descriptions have not been updated to allow graduates to count their research or experience as relevant scientific and technical coursework for certain positions. FDA has used Cures Act flexibilities to create new critical positions that adapt to changing academic training, technology, and developments in scientific fields that are not adequately captured under the traditional job descriptions.²³

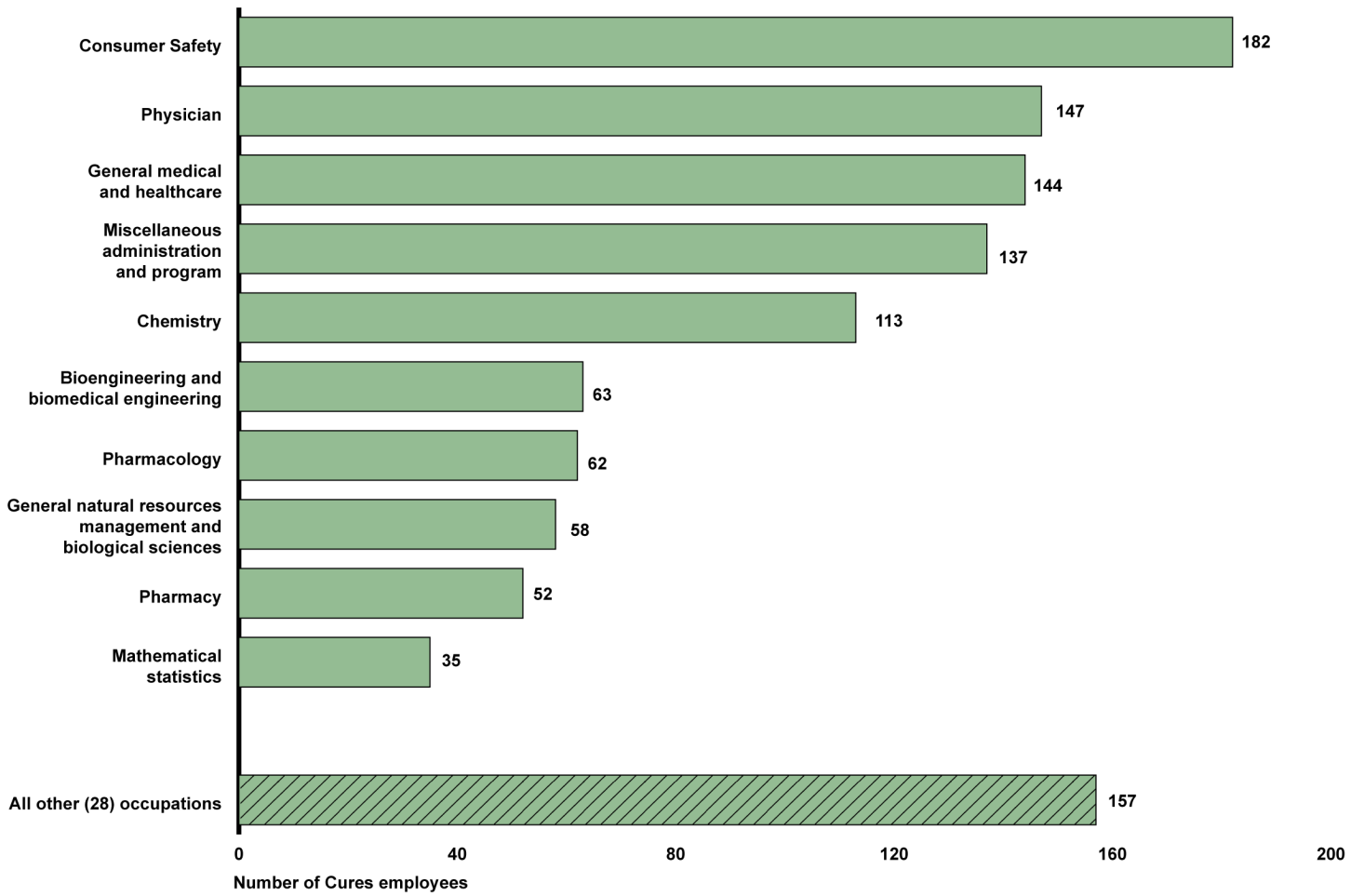
²²FDA officials told us that instead of using traditional occupational job families and grading criteria for the GS and Federal Wage Classification Systems, Cures Act positions use a Statement of Duties and Leveling Guide to capture the position's duties and to determine the position's pay band. As a result, the agency can tailor the duties as needed and not rely on traditional OPM classification criteria to determine the position's level of responsibility, which may be outdated or non-existent for some emerging scientific fields.

²³OPM works with agencies to establish new classifications and revise existing occupational classifications that are used under traditional hiring. This process involves OPM publishing draft standards, revising standards based on agency comment, publishing final standards, and developing guidance to agencies on how to implement the classification standards, among other steps. OPM officials have previously told us that updating the standard for a specific occupation is a resource-intensive process that often takes 6 months to a year to complete, and that reviewing an occupational family, which includes a number of individual occupations, can take multiple years to complete. See GAO, *Human Capital: OPM Needs to Improve the Design, Management, and Oversight of the Federal Classification System*, [GAO-14-677](#) (Washington, D.C.: July 31, 2014).

Offering Higher Salaries to Recruit and Retain Employees. Officials from all three centers in our review said that they are able to use Cures Act pay flexibilities to offer higher pay to job candidates, which allows them to better compete with the private sector. Cures Act pay flexibilities also help retain existing staff by enabling the centers to convert them to Cures Act pay bands with higher pay maximums, which may encourage experienced staff to stay at FDA instead of leaving for the private sector. While Cures Act pay flexibilities help FDA offer higher salaries than it could under traditional hiring, an FDA analysis of 2019 data found that Cures Act salaries continued to be lower than market medians for equivalent positions. For example, FDA found that the midpoint Cures Act salary for a supervisory regulatory counsel at the Band F level was 10 percent less than the estimated market median for an equivalent position in the private sector. Further, FDA found that the differences between Cures Act salaries and estimated market medians widened at the higher Cures Act bands. Even with these differences, FDA officials told us that use of the Cures Act hiring and pay flexibilities, combined with other tools available to the agency more generally, help improve their ability to retain medical product staff. These tools include student loan repayment programs, flexible work schedules, and efforts to create an environment that engages employees.

FDA has used Cures Act flexibilities to hire and retain employees in mission-critical occupations. As of October 2021, FDA reported having 1,150 employees under the Cures Act pay system, up from 379 at the end of fiscal year 2020. A previous FDA analysis of Cures Act hiring found that most were existing FDA employees who were converted or recruited from other pay systems, and most were in one of the three medical product centers. Four of the top five occupations—consumer safety officers, physicians, general medical and healthcare staff, and chemists—corresponded to mission-critical occupations that FDA reported in 2018 as having salaries that were at least 20 percent lower than the average private sector salary for the same occupations. See figure 2 for a full breakdown of the number of Cures Act employees by occupation.

Figure 2: Number of Cures Act Employees at FDA by Occupation, October 2021



Source: GAO analysis of data from the Food and Drug Administration (FDA). | GAO-22-104791

Accessible Data for Figure 2: Number of Cures Act Employees at FDA by Occupation, October 2021

Category	Number of Cures employees
Consumer safety	182
Physician	147
General medical and healthcare	144
Miscellaneous administration and program	137
Chemistry	113
Bioengineering and biomedical engineering	63
Pharmacology	62
General natural resources management and biological sciences	58
Pharmacy	52
Mathematical statistics	35
All other (28) occupations	157

Note: The "Miscellaneous Administration and Program" occupation category includes Cybersecurity Specialist, Data Scientist, Digital Health Specialist, and Regulatory Counsel.

The three medical product centers in our review vary in how they use the Cures Act hiring and pay flexibilities, according to FDA officials and documents we reviewed. Officials from these three medical product centers reported using Cures Act flexibilities to prioritize hiring certain staff, such as in the following examples.

- CDER first implemented Cures Act flexibilities to hire and convert existing mission-critical executive and supervisory positions but has since begun to use Cures Act flexibilities to the greatest extent possible for hiring and retention at all levels. It expanded its use of Cures Act flexibilities in 2020 to include recruitment for eligible vacant positions, such as scientists that specialize in rheumatology, anesthesiology, cardiology, neuroimmunology, and rare diseases. CDER officials told us they would prefer to use Cures Act flexibilities as the primary way to hire and retain staff going forward, in part to create more consistency across the center—so that similarly qualified staff receive comparable pay.
- CBER has primarily used Cures Act flexibilities to fill senior leadership positions but has also used them in some individual cases that presented difficult recruitment or retention issues, such as oncologists and hematologists. CBER has also used Cures Act flexibilities to encourage existing staff to take on supervisory roles by offering them better pay. However, budgetary concerns related to the higher pay afforded by the Cures Act flexibilities have constrained CBER's use of

the flexibilities, according to center officials. Because CBER is a relatively small center within the agency and has a relatively small overall budget, the officials noted that they have decided to limit the number of employees they hire under or convert to Cures Act pay bands to avoid potential long-term budgetary challenges associated with paying those higher salaries.

- CDRH has primarily focused on using Cures Act flexibilities to fill management supervisory positions. For non-supervisory positions, CDRH officials told us they have used Cures Act flexibilities to fill positions that require a unique skillset the center has had difficulty hiring for in the past, such as regulatory policy analysts and counsel, physicians, data scientists, and radiologists.

While all three centers try to use the Cures Act flexibilities to hire and retain staff, officials acknowledged challenges. Officials noted that all nine of the hiring authorities the agency can use, including the Cures Act authority, entail their own sets of processes, such as approval levels and pay limits, which officials said complicate efforts to facilitate hiring across the organization. For example, justifying the use of Cures Act flexibilities is paperwork-intensive, according to CDER officials, and the hiring manager needs to be able to demonstrate how a specific person is outstanding for a position.¹ For many hiring managers trained on using traditional hiring, which does not generally involve creating justifications for specific positions or personnel, the process can be time-consuming.

FDA has taken steps to increase its use of Cures Act flexibilities by training staff to use these authorities, according to officials from CDER, CBER, and OTS. For example, FDA implemented training of OTS staff to deepen knowledge of Cures Act policy and procedures, and OTS staff in turn provide training to the centers on how to use the Cures Act hiring flexibilities. OTS said that they also established regular staff check-in meetings to field questions about using the Cures Act flexibilities. In addition, OTS officials said that they have shifted from a generalist system—in which human resources staff are expected to understand the details of all nine hiring authorities—to a system with specialized teams dedicated to each authority and type of hiring. CDER told us that they

¹Candidates for Cures Act positions must be “outstanding and qualified” in order to be eligible for appointment. “Outstanding” is determined by the agency as either based on performance scores (for existing HHS employees, which includes those at FDA) or on center-specific qualitative criteria for “outstanding” credentials, which must be included in the position justification and be consistent with those for other Cures Act justifications. “Qualified” is interpreted by the agency as meeting the OPM standards and specialized experience requirements for the occupational series of the position.

also conduct their own trainings within their centers in order to complement agency-wide training.

FDA Follows Some Leading Workforce Planning Practices but Does Not Have an Agency-Wide Strategic Workforce Plan

According to leading practices for effective workforce planning we have identified, agencies should (1) determine needed skills and competencies and develop strategies to address gaps, (2) monitor and evaluate progress toward human capital goals, and (3) develop a strategic workforce plan to coordinate these strategies and align them with agency-wide goals.²

While FDA follows leading practices by determining needed skills and developing strategies to address gaps, and is taking steps to monitor progress toward human capital goals, it lacks performance measures to evaluate the effectiveness of its strategies. Further, FDA does not have an agency-wide strategic workforce plan to coordinate these activities across the three medical product centers in our review to ensure they are aligned with the agency’s mission and programmatic goals. (See table 4.)

Table 4: FDA Workforce Planning Activities for Medical Product Staff As Compared to GAO-Identified Leading Practices for Effective Workforce Planning

Leading practice	Alignment between FDA actions and leading practices
Determine needed skills and develop strategies to address gaps	Aligned
Monitor and evaluate progress toward human capital goals	Partially aligned
Develop a strategic workforce plan	Not aligned

Legend: ● = Aligned with leading practices; ◐ = Partially aligned with leading practices; ○ = Not aligned with leading practices

Source: GAO analysis of Food and Drug Administration documents and interviews with officials. | GAO-22-104791

²[GAO-04-39](#).

Determine Needed Skills and Develop Strategies to Address Gaps

The three medical product centers in our review told us that they conduct yearly planning activities to determine the skills and competencies they need to achieve programmatic results and develop strategies to address skill and competency gaps, in line with leading practices of effective workforce planning that we have identified. Every fiscal year, OHCM produces a workforce profile report containing high-level data to inform workforce planning for the three medical product centers. These reports include data such as Federal Employee Viewpoint Survey results, retirement eligibility trends, workforce demographics, and personnel gains and losses.³ Since fiscal year 2019, the three centers have used these reports, along with additional information and analyses of their own (such as anticipated workloads), to create talent acquisition plans that forecast their hiring needs and identify specific positions they wish to hire for over the upcoming fiscal year, OTS officials told us. The centers also produce strategy memos documenting their priorities for use of the Cures Act flexibilities to recruit and retain medical product staff. OTS meets with medical product center staff during the annual planning process to provide input on each center's plan, though the final decisions on which positions to include reside with the centers, OTS officials said. Once the medical product centers have completed these plans and memos, they provide them to OTS, which uses them to guide agency-level recruitment activities throughout the year, the officials said.

Monitor and Evaluate Progress

FDA has taken steps to monitor and evaluate progress toward human capital goals, in line with another leading practice of effective workforce planning we have identified. In addition to the OHCM workforce profile reports mentioned previously, the centers receive biweekly reports that include data such as staff gains and losses, hires by authority, and total counts of full-time staff. At the end of each fiscal year, staff from each of the three centers meet with OTS to evaluate the extent to which they met their hiring goals and discuss any lessons learned for the future, OHCM and OTS officials told us. FDA also hired three external contractors to conduct comprehensive assessments of the agency's human capital

³OPM's Federal Employee Viewpoint Survey is an annual survey that measures employees' overall perceptions of their workplace. The survey is administered to a sample of federal employees across the government.

program and implementation of the Cures Act flexibilities. Additionally, FDA is working to implement a new applicant tracking system for use by human capital staff, which officials say will provide greater transparency into where a vacancy is in the hiring process and improve access to data, such as how long it takes to hire new employees (“time-to-hire”).

However, FDA does not have performance measures in place to assess whether the agency executed particular human capital strategies as intended and achieved the goals of these strategies, as called for by the leading practices we have identified. For example, while the biweekly and annual workforce reports might serve as useful tools for staff to monitor overall progress toward medical product center hiring goals, these reports do not measure the contributions of specific activities or strategies to these goals, such as the use of different recruitment practices or hiring authorities. Similarly, OHCM and OTS officials told us they primarily measure the effectiveness of Cures Act flexibilities by reviewing retention rates of the medical product centers as a whole and of medical product positions eligible for the flexibilities, and they pointed to the fact that retention has improved since 2018 as evidence that the flexibilities have been effective in retaining employees. However, these officials also told us that other factors may have contributed to the improved retention, such as economic uncertainty and FDA’s maximum telework policy in the wake of the Coronavirus Disease 2019 (COVID-19) pandemic. FDA does not currently use other outcome-focused measures to gauge the success of the Cures Act flexibilities or other human capital strategies. Such measures could include, for example, time-to-hire data by hiring authority, data on recruitment sources for applicants and successful candidates, and measures that evaluate the outcomes of changes made to hiring processes.

Develop a Strategic Workforce Plan

FDA lacks an agency-wide strategic workforce plan, as called for by leading workforce planning practices we have identified (see text box). The last time FDA had an agency-wide strategic workforce plan was nearly a decade ago—a plan for fiscal years 2010 through 2012 that was developed in response to a recommendation we made in 2010.⁴ This plan predated the establishment of the Office of Human Resources in 2012, which was further reorganized into OHCM and OTS in 2018. Because of

⁴GAO, *Food and Drug Administration: Opportunities Exist to Better Address Management Challenges*, [GAO-10-279](#) (Washington, D.C.: Feb. 19, 2010).

this timing, current agency officials we spoke with were not aware that that plan had been developed. More recently, FDA drafted, but did not finalize, a new agency-wide strategic workforce plan for fiscal years 2017 through 2020, agency officials told us. According to these officials, the plan was never finalized due to the agency's decision to conduct decentralized workforce planning instead.

What Is Strategic Workforce Planning and Why Is It Important?

Strategic workforce planning aligns an organization's human capital program with its current and emerging mission and programmatic goals, and develops long-term strategies for acquiring, developing, and retaining staff to achieve those goals. This process—in conjunction with identifying skills and competencies and analyzing gaps—enables the organization to be agile, resilient, and responsive to current and future demographic and technological trends, as well as other demands. Our prior work has found that strategic workforce planning is particularly important for agencies with science and technology missions such as FDA, which must compete for talent with the private sector, universities, and non-profit research centers, and keep up with scientific advancements.

Source: [GAO-19-181](#); [GAO-21-461T](#) | [GAO-22-104791](#)

Instead of developing agency-wide strategic workforce plans, FDA now uses a decentralized workforce planning process in which each individual center and office across the agency, including the three medical product centers in our review, conducts its own workforce planning, officials told us. Specifically, as described above, the three centers develop yearly talent acquisition plans and create strategy memos outlining how they plan to use the Cures Act flexibilities to meet their workforce needs. However, while these plans and memos align with the leading practice to determine hiring needs and develop strategies to meet them, they do not contain the kind of long-term, coordinated goals and strategies for the workforce—aligned with agency-wide mission and programmatic goals—that would be part of an agency-wide strategic workforce plan. Absent an agency-wide strategic workforce plan, FDA lacks a plan to monitor progress toward agency-wide human capital goals, which is inconsistent with leading practices.

FDA has taken steps to conduct strategic planning that incorporates some goals and strategies related to the workforce; however, this planning does not constitute a strategic workforce plan, which would include long-term, coordinated goals and strategies for acquiring, developing, and retaining staff that are in line with broader FDA mission goals. Examples of the planning FDA has conducted include the following.

- **Office of Human Resources Strategic Plan (fiscal years 2016-18):** This plan outlined broad goals and objectives for FDA's former Office of Human Resources, the predecessor of OHCM and OTS. These goals included strengthening the Office of Human Resource's internal capacity, improving coordination with hiring managers, and enhancing the FDA employee experience. However, while the plan recognized the challenges facing FDA in recruiting, hiring, and retaining for mission-critical occupations, as well as the importance of developing a strategic workforce plan, it did not include the strategies for addressing these challenges that a strategic workforce plan would contain.
- **Succession Management Strategic Plan (fiscal years 2017-20):** This plan provided a strategy to develop the next generation of leaders across the agency. It included an analysis of leadership positions at high risk of retirement and attrition and outlined planned initiatives to develop internal successors to these positions, such as leadership training programs. However, while this plan is an example of a coordinated strategy in response to a specific workforce challenge, it focused on succession planning rather than workforce planning more broadly. Thus, it did not constitute a strategic workforce plan.

Other recent reviews have similarly found FDA's agency-wide strategic workforce planning to be lacking and recommended that the agency take further action, as in the following examples.

- In 2018, an OPM audit found that while FDA had developed human capital goals and centers had developed plans in support of the goals, there was no evidence to show that activities related to the plans were coordinated and monitored agency-wide to maximize efforts.⁵ In addition, OPM recommended that FDA develop a formal agency strategic plan to address crosscutting issues and facilitate collaboration across the agency on management challenges.
- In 2020, an evaluation conducted by Booz Allen Hamilton found that FDA lacked an agency-wide, systematic approach for its human capital functions.⁶ The authors asserted that such an approach would

⁵U.S. Office of Personnel Management, *Human Capital Management Evaluation, Department of Health and Human Services, Food and Drug Administration: May-July 2018* (Washington, D.C.: Dec. 20, 2018)

⁶Booz Allen Hamilton, *FDA Interim Hiring and Retention Assessment* (April 13, 2020). Booz Allen Hamilton is a management consulting firm that FDA hired to assess its hiring and recruitment practices.

be one that documents linkages between center-level and agency-wide goals, guidance, processes, and resources. Further, they noted that without a coordinated agency-wide strategy, recruitment and retention functions may be ineffective, and staff may lack full understanding of the factors behind this ineffectiveness and have limited ability to make improvements. The authors recommended that FDA develop and implement a systematic human capital strategic plan that includes agency-wide goals and steps to achieve them. In addition, they recommended that FDA identify, capture, and regularly review performance measures to assess the outcomes of human capital activities.

- In 2020, FDA commissioned an internal report on retention risk across the agency. The resulting report found that, in some cases, human capital activities at FDA were not sufficiently centralized, with the centers and offices performing their own functions.⁷ The authors noted this can lead to insufficient sharing of best practices, create fragmentation, and reduce consistency of agency-wide human capital messaging. The report's authors recommended that FDA senior leaders and governance bodies continue to build a coordinated, agency-wide approach to recruiting, hiring, and retention, in line with the recommendations made in the Booz Allen Hamilton report.
- In 2020, an evaluation by the MITRE Corporation of FDA's implementation of the Cures Act flexibilities recommended that FDA establish an agency-wide strategy for use of these flexibilities to avoid actual or perceived inequities across the centers.⁸ MITRE also found that FDA's centers have instituted additional restrictions of their own on the use of Cures Act flexibilities, which have caused hiring delays and may be perceived as overly bureaucratic.

In addition, the agency does not have a process to regularly update an agency-wide strategic workforce plan should one be developed, which is inconsistent with federal internal control standards that call for agencies to use timely, relevant information that is reviewed and updated in an

⁷U.S. Food and Drug Administration, *Retention Risk Analysis* (2020).

⁸MITRE Corporation, *Health FFRDC Project Close-Out: FDA Cures Support* (September 2020). MITRE Corporation is a consulting firm that FDA hired to assess its implementation of the Cures Act flexibilities.

ongoing, iterative process to achieve agency objectives.⁹ Having a process in place to regularly update a strategic workforce plan may be particularly important for federal agencies within the executive branch that experience regular turnover of agency leadership to ensure that valuable institutional knowledge is not lost in the long term. We have previously found that, during transitions, a strategic workforce plan can serve as a roadmap to guide agencies from the current to the future workforce needed to achieve their goals.¹⁰ Given FDA's recent period of transitions, including the human capital office reorganization, implementation of Cures Act flexibilities, and the challenges facing the agency as it responds to the COVID-19 pandemic, a strategic workforce plan and a process in place to keep that plan up to date would provide a coordinated direction to guide the agency and its workforce through these changes.

Until FDA develops an agency-wide strategic workforce plan and establishes a process to keep it up to date, it will not be able to ensure that the human capital strategies undertaken by individual centers and offices, including use of Cures Act flexibilities, are and will remain consistent with the agency's overall and long-term needs and goals. For example, officials from OHCM, OTS, and two of the three medical product centers told us that the implementation of Cures Act flexibilities is starting to create pay disparities and competition between centers that use these flexibilities and those that use them to a lesser extent or are ineligible. In addition, in 2020 Booz Allen Hamilton found that inconsistent implementation of Cures Act flexibilities was contributing to perceptions of staff poaching between centers. FDA officials told us they are concerned about the effects of these real and perceived disparities on employee morale.

Conclusions

FDA partially follows leading practices of effective workforce planning for its medical product staff; however, it does not have an agency-wide

⁹GAO, *Standards for Internal Control in the Federal Government*. [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

OHCM officials told us they plan to work with FDA's Human Capital Strategic Council to gauge agency interest in developing an agency-wide strategic workforce plan in 2022.

¹⁰[GAO-10-226](#).

strategic workforce plan to guide and coordinate its workforce planning generally across the agency and for the medical product staff in the three medical product centers. These staff are responsible for carrying out FDA's mission to protect public health, and their skills and competencies are critical to ensuring the overall success of the agency in achieving this mission. Further, should FDA develop such a strategic workforce plan, as it did in response to a recommendation we made in 2010, it does not have a process to regularly update it on an ongoing basis. Without an agency-wide strategic workforce plan, as called for by leading practices, FDA lacks reasonable assurance that the strategies pursued by individual medical product centers are aligned with agency-level needs and goals. Establishing a process to develop and maintain such a plan would help ensure that efforts to conduct agency-wide planning are seen through to completion and updated moving forward. In addition, although FDA's human capital offices and medical product centers monitor overall progress toward hiring goals, FDA does not have performance measures in place to evaluate its human capital strategies or identify ways to improve these strategies.

Recommendations for Executive Action

We are making the following two recommendations to the FDA.

- The Commissioner of FDA should develop and implement an agency-wide strategic workforce plan to document agency-wide human capital goals and strategies, which should include elements to ensure FDA is able to monitor and evaluate progress toward its human capital goals, such as performance measures to assess the effectiveness of these strategies. (Recommendation 1)
- The Commissioner of FDA should establish a process to update its agency-wide strategic workforce plan on an ongoing basis. (Recommendation 2)

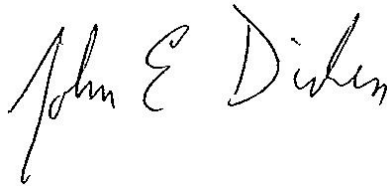
Agency Comments

We provided a draft of this report to HHS for review and comment. In its written comments, which are reproduced in appendix I, HHS concurred with our recommendations and stated that FDA believes there is opportunity to better integrate the human capital functions through strategic human capital planning in partnership with the centers and improve its systems approach. Additionally, HHS stated that FDA is in the

process of developing an integrated strategic human capital plan that includes high-level goals and objectives, as well as a process for updating the plan on an annual basis. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

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



John E. Dicken
Director, Health Care

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

**Appendix I: Comments from the Department of
Health and Human Services**



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

December 16, 2021

John E. Dicken
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Dicken:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, ***"FDA WORKFORCE: Agency-wide Workforce Planning Needed to Ensure Medical Product Staff Meet Current and Future Need"*** (GAO-22-104791).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – FDA WORKFORCE: AGENCY-WIDE WORKFORCE PLANNING NEEDED TO ENSURE MEDICAL PRODUCT STAFF MEET CURRENT AND FUTURE NEED (GAO-22-104791)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report. We appreciate GAO's recognition of workforce planning at FDA.

Recommendation 1

The Commissioner of FDA should develop and implement an agency-wide strategic workforce plan to document agency-wide human capital goals and strategies, which should include elements to ensure FDA is able to monitor and evaluate progress toward its human capital goals, such as performance measures to assess the effectiveness of the strategies. (Recommendation 1)

HHS Response

HHS concurs with GAO's recommendation.

FDA agrees that developing and implementing an agency-wide strategic workforce plan to document human capital goals and strategies is valuable. FDA believes there is opportunity to better integrate the human capital functions through strategic human capital planning in partnership with the centers and improve its systems approach.

Recommendation 2

The Commissioner of FDA should establish a process to update its agency-wide strategic workforce plan on an ongoing basis. (Recommendation 2)

HHS Response

HHS concurs with GAO's recommendation.

FDA agrees with this recommendation. On November 4, the Office of Operations Office of Human Capital Management (OHCM) facilitated a workgroup consisting of staff from the Office of Talent Solutions (OTS) and Human Capital representatives from each of FDA's Centers and the Office of Regulatory Affairs (ORA). FDA is in the process of developing an integrated strategic human capital plan that includes high-level goals and objectives, as well as a process for updating the plan on an annual basis.

Accessible Text for Appendix I: Comments from the Department of Health and Human Services

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Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Gerardine Brennan (Assistant Director); Matthew Green (Analyst-in-Charge); Sean Miskell, and Marissa Esthimer made key contributions to this report. Also contributing were George Bogart, Laurie Pachter, and Vikki Porter.

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