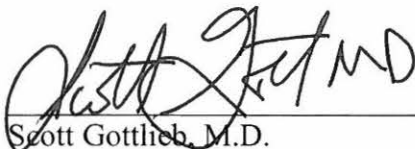


**FDA 21st Century Cures Workforce Planning
Report to Congress**

June 2018

A handwritten signature in black ink, appearing to read "Scott Gotthieb MD". The signature is written over a horizontal line.

Date 5-21-18

Scott Gotthieb, M.D.
Commissioner of Food and Drugs

Table of Contents

FDA 21 st Century Cures Workforce Planning Report to Congress	1
Contents	1
Letter from the Commissioner	3
Introduction.....	5
Background	6
Analysis of FDA Workforce Needs.....	8
Rapid Advancements in Medicine and Technology	8
FDA’s Evolving and Increasing Responsibilities.....	8
Market Forces	9
Hiring and Retaining Supervisors.....	10
Attrition.....	10
Patchwork of Authorities	12
Strategic Plan for Recruitment and Retention at FDA.....	13
Improving FDA’s Overall Hiring Process	13
Implementation of Cures HR Authority	14
Additional Recruiting Efforts	15
Use of Placement Agencies	16
Recruitment through Academic Institutions	17
Hiring Bonuses (Recruiting Incentives).....	18
Direct Hire Authority.....	18
Other Pay Authorities	18
Pathways Program	19
Social Media Strategy.....	19
Retention Efforts.....	19
The FDA Employee Value Proposition.....	20
Diversity and Inclusion	20
Succession Planning.....	21
Leadership Development and Training Offerings	22
Commissioner’s Recommendations.....	23

Letter from the Commissioner

The Food and Drug Administration (FDA or the Agency) depends on a highly skilled workforce to carry out its mission to help ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and to reduce death and disease associated with tobacco products. As the science that we regulate becomes more complex and specialized, so too must the skills and expertise of our staff. In December 2016, Congress passed the 21st Century Cures Act (Cures), which, among other things, gave the Agency critical new authorities to help advance medical product innovation. I am grateful that Congress recognized that the expertise of our professional staff and the opportunities to apply their skills—and use cutting-edge science—are essential for maintaining the high quality of our work and so included in the Act new human resources (HR) authorities for FDA.¹ This authority will allow us to better build and maintain the highly talented workforce needed to meet the challenges of today’s rapid advances in science, medicine, and technology.

The Cures HR authorities for hiring and compensation provide FDA with two important talent management tools. First, FDA was granted flexibility to help simplify and expedite the process for hiring individuals for certain scientific, technical, and professional occupations. Second, the law gave FDA the authority to establish a new pay authority to enable the Agency to better compete with the private sector and academia to recruit and retain outstanding, highly qualified individuals for these positions.

FDA created a Cures HR Working Group with representatives from across the Agency soon after the Act was passed; that body has been hard at work on the initial implementation of the new HR authority. The Working Group conducted extensive research on such foundational issues as other agencies’ use of a similar HR authority, recommended practices, and evaluated options. The Working Group has factored this body of data into its decisions on the most appropriate and effective implementation of the Cures HR authority for FDA. We were proud to begin using the Cures HR authority in February 2018 on critical recruitment and retention priorities identified by our medical product Centers.

To maximize this opportunity, the Agency has embarked on a deliberate and strategic approach to augmenting and maintaining a top-quality 21st century workforce. This report describes the efforts we have taken to date as well as the work underway to improve recruitment and decrease our time to hire and to retain our talented staff. The Cures HR authority is an important addition

¹ Public Law 114-255, the “21st Century Cures Act,” included a Subtitle G entitled “Improving Scientific Expertise and Outreach at FDA.” In relevant part, Subtitle G adds a new section 714A to the Federal Food, Drug, and Cosmetic Act entitled “Hiring Authority for Scientific, Technical, and Professional Personnel.” Throughout this report, we refer to this new authority as the “Cures HR” authority.

to our recruitment and retention toolbox. We have only begun to tap its potential. We will continue to evaluate the opportunities that the Cures HR authorities provide FDA and use these authorities in a way that balances flexibility with equity, fairness, and long-term fiscal responsibility.

Scott Gottlieb, M.D.
Commissioner of Food and Drugs

Introduction

The 21st Century Cures Act (Cures) was enacted on December 13, 2016. The legislation includes a variety of provisions that affect the activities of FDA and other agencies within the Department of Health and Human Services (HHS) on a broad range of topics related to the discovery, development, review, approval, and delivery of medical products. Cures also provided new authority to help FDA improve its ability to recruit and retain scientific, technical, and professional experts. Section 3072 of the Cures Act (21 U.S.C. 379d-3a(d)) requires that the Secretary of HHS submit a report on workforce planning for FDA and its need for qualified staff. This provision states:

(1) IN GENERAL. --- Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified individuals for scientific, technical, or professional positions, including ---

(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary's strategic plan for addressing such needs, including through use of the authority under this section; and

(B) a recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of ---

(i) recruitment through nongovernmental recruitment or placement agencies;

(ii) recruitment through academic institutions;

(iii) recruitment or hiring bonuses, if applicable;

(iv) recruitment using targeted direct hiring authorities; and

(v) retention of qualified scientific, technical, and professional employees using the authority under this section, or other applicable authorities of the Secretary.

(2) RECOMMENDATIONS.---The report under paragraph (1) may include the recommendations of the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.

The following report is in response to this directive.

Background

Cures was a significant legislative achievement that coincided with a pivotal moment in medicine and technology. This legislation grew out of a bipartisan, bicameral recognition that at this moment in science, the opportunity exists to fundamentally alter the course of many human ailments, and even cure diseases or reverse the effects of injury and illness. Cures included provisions that have the potential to impart far-reaching effects on scientific advancements in medical product development. The new law complements many efforts underway at FDA, all aimed at transforming the way the Agency supports product development and marketing authorization while maintaining our reputation as the gold standard for safety and effectiveness.

Cures provides the Agency with important tools that help it continue to meet its mission to protect and promote the public health. Ensuring timely implementation of Cures is a top Agency priority and will help patients realize the benefits of medical innovation. By providing product developers a clear and predictable path for new advances, patients and consumers can realize the benefits of innovations while maintaining confidence that the resulting medical products are safe and effective.

Congress recognized that building and retaining talented staff is essential to FDA's ability to realize the promise of Cures as well as successfully carry out the Agency's many other public health responsibilities. Both HHS and FDA are committed to maintaining a highly qualified workforce. This commitment is captured in [HHS Strategic Plan \(FY 2018-2022\)](#) Objective 5.2, Manage Human Capital to Achieve the HHS Mission, which outlines efforts to:

- Deploy creative and strategic recruitment strategies to target talent to fill mission-critical occupations;
- Recruit and retain the most qualified candidates to best meet the needs of the populations served by the Department;
- Increase the efficiency and effectiveness of recruitment efforts by partnering with hiring managers and leveraging data to make informed decisions regarding recruitment and retention strategies;
- Use existing flexibilities and pursue new retention incentives to ensure HHS retains the highest caliber workforce; and

Summary of the 21st Century Cures Act

- Builds on FDA's ongoing work to incorporate patient perspectives into the medical product development process and FDA's review process
- Encourages continued modernization of the conduct and design of clinical trials
- Supports continuing efforts to qualify drug development tools, such as biomarkers, to promote more efficient development of drug and biologics
- Establishes a Breakthrough Device program to help expedite the review of certain innovative devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions
- Establishes a new program to facilitate and expedite the development and review of certain regenerative medicine products
- Gives the Agency new authority to recruit and retain outstanding and qualified candidates for scientific, professional, and technical positions

Focus of
this
Report

- Improve workforce planning efforts by integrating succession management activities into efforts to retain employees and manage knowledge transfer within government-wide and agency-specific mission-critical occupations and other shortfall areas.

FDA also recognizes the importance of a world-class workforce, as reflected in [*Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap*](#). This report details how FDA will identify current workforce needs, as well as our strategies for addressing workforce needs—including the Agency's recruitment and retention plan for hiring qualified candidates for scientific, technical, and professional positions to achieve the goals of HHS's strategic plan.

The importance of a highly qualified workforce led Congress to include a new hiring and pay authority (referred to in this report as the Cures HR authority) for FDA in Cures. This authority provides tools to efficiently recruit and retain scientific, technical, and professional staff needed to continue advancing innovation and fulfilling FDA's mission. To date, the Agency has been using a patchwork of hiring and pay authorities that, while important, were not created solely for FDA and have certain limitations. Cures provided FDA the flexibility and discretion to design a human capital framework that is specifically tailored to meet the specialized needs of a science-based public-health regulatory agency.

Under the Cures HR authority, the Commissioner can appoint individuals into the competitive service and can set salaries up to the annual maximum of \$400,000 established in Title 3, section 201, of the United States Code. FDA can develop its own Alternative Pay System (APS), giving the Agency enhanced flexibility (and guidelines) to offer salaries for highly skilled professionals that are closer to, and more competitive with, market salaries. Cures also provided a hiring flexibility to speed time to hire.

The remainder of this report will: (1) describe the Agency's critical need for qualified individuals for scientific, technical, and professional positions; (2) provide an analysis of workforce requirements at FDA; and (3) detail a recruitment and retention plan which includes the Agency's strategic approach for using the Cures HR authority.

Analysis of FDA Workforce Needs

FDA's workforce needs have changed significantly, and in a relatively short time, because of the Agency's new and expanded authorities (e.g., Cures) as well as the increasing speed of medical and scientific advancement. The Agency had slightly more than 8,000 employees just 10 years ago, and staff numbers have now more than doubled to 17,000. The number of full-time equivalent positions in the Center for Drug Evaluation and Research (CDER) alone has increased 50 percent since 2012. The need to rapidly recruit highly skilled and experienced staff has been a challenge for the Agency to fully meet the needs of the modern FDA, which is responsible for regulating more than 20 percent of the nation's Gross Domestic Product. Some of the principal factors driving the Agency's workforce needs are discussed below.

Rapid Advancements in Medicine and Technology

We are at a point in science where new medical technologies hold the promise of better treatments for a widening number of serious and difficult conditions. Over the last few decades, science has enabled fundamental advances in understanding the genetic and protein bases of human disease. These developments are already translating into new medical products that provide life-altering treatments—and even cure—a growing number of diseases. As the products FDA regulates, such as regenerative medicines, become more complex and specialized, FDA staff must remain current with the latest advances in science so they can continue to support the pharmaceutical and device industries as they develop treatments and bring them to market.

These new advances mean that FDA is recruiting professionals in a variety of disciplines to carry forward the Agency's responsibilities. The Cures Act created or enhanced a number of programs that require specialized staff. The Act also included provisions addressing patient-focused drug development, regenerative medicine, innovative clinical trial designs, qualification of drug development tools, antibiotic approvals, and breakthrough devices, to name a few. These programs, as well as much of the Agency's other ongoing work, will require FDA to seek out the best and brightest scientific minds in medicine, biostatistics, genetics, biomedical engineering, and health informatics, among others, to advance this important work.

FDA's Evolving and Increasing Responsibilities

Over the years, FDA's responsibilities have increased significantly. Congress has entrusted the Agency with implementing a variety of important new regulatory programs. FDA estimates that over 10 years, it will need to add approximately 200 new staff to implement Cures requirements in emerging areas such as regenerative medicine, breakthrough devices, qualification of biomarkers, novel clinical trial designs, and the use of real-world evidence. Every 5 years, the medical product Centers negotiate new user-fee agreements with the medical product industry to establish new user-fee goals and the funding required to meet those goals. These agreements often contain commitments with respect to review program enhancements (e.g., development of new guidance documents) in addition to procedural goals for review timeframes. The latest user-fee statute, the FDA Reauthorization Act of 2017 (FDARA), is similar to previous user-fee

legislation in that it contains a number of new activities for FDA to implement. Some of the user-fee commitments also contain hiring goals for FDA.

In the last 10 years, other major legislative achievements have increased FDA's regulatory authorities. In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act, requiring FDA to establish a new center to implement the comprehensive system of health-related tobacco product regulation laid out in the statute. In 2011 the Food Safety Modernization Act was enacted, conferring new enforcement authorities related to food safety standards, giving FDA new tools to hold imported foods to the same standards as domestic foods and directing it to build an integrated national food safety system in partnership with state and local authorities. The Agency has been tasked with implementing the Drug Supply Chain Security Act (2013) (which enhances the security of the drug distribution supply chain to protect consumers from exposure to drugs that may be counterfeit or otherwise harmful) and the Drug Quality and Security Act (2013) (which requires an electronic and interoperable system to identify and trace certain prescription drugs throughout the United States to protect patient safety). Most recently, Congress passed FDARA (mentioned above), which reauthorized the user fees for CDER, the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH).

These laws represent differing and important advances in protecting the health and safety of the American people, and they reflect the dynamic nature of our jurisdiction and the rapidly evolving legislative landscape. With these new responsibilities comes the imperative to staff the efforts appropriately to properly execute the laws Congress enacted.

Market Forces

The experienced and specialized doctors, scientists, and other professionals that FDA seeks are also in high demand in academia and industry. In some cases, such as mathematical statisticians, pharmacokineticists, and doctoral-level economists, FDA must compete with other federal agencies and private-sector entities to hire from a very small pool of graduates every year. Not only are small numbers of certain specialists an issue, but FDA has a difficult time competing with private-sector salaries and benefit packages. Market research shows that many of FDA's mission-critical occupations (MCOs), such as toxicologists, pharmacists, and veterinarians, are the occupations with the largest gaps in government pay compared to the private sector.² The table on the next page shows just how large the differential is for specific

² In 2017, FDA contracted with a compensation specialist to conduct a detailed comparative analysis of FDA salaries to the 2016 Mercer Strategic Industry Rewards Solutions (SIRS) Life Sciences Benchmark salary survey. MCOs were matched to the Mercer job codes. Average actual FDA salaries (with and without locality pay) were then compared to the Mercer mean base salaries by grade (for both non-supervisory and supervisory positions). The results of that analysis support FDA's own findings that average FDA salaries are significantly less than private-sector averages. The table on the next page shows the job series titles where average FDA salaries were found to be more than 20 percent below those in the private sector.

occupations. This pay gap is a significant issue in recruiting and retaining qualified mission-critical employees. Finally, Agency supervisors report that as employees are trained at FDA and gain regulatory experience in their fields over 2 or more years, they become extremely attractive to industry and other private entities, which are sometimes able to attract such employees away from the Agency with higher salary and benefit packages. Losing employees in this manner represents the loss of a significant investment in time and other resources and creates a lag in full productivity when a new person is hired for a vacated position.

Hiring and Retaining Supervisors

Interviews with FDA leaders indicate that supervisory positions are particularly difficult to fill. One of the reasons cited is that FDA is not able to pay salaries to supervisors that make it attractive to take on the additional responsibilities of being a manager. In fact, often due to the differences in existing hiring and pay authorities, some managers find themselves supervising individuals with higher salaries. Market analysis using the 2016 Mercer SIRS Life Sciences Benchmark salary survey found that supervisors are paid significantly less at FDA than in the private sector, adding to the challenge of recruiting and retaining them. The pay disparity with market salaries grows as positions increase in responsibility in the leadership chain at FDA. At the Senior Executive Service (SES) level, candidates from the private sector often report that their current salaries are well above the \$400,000 Cures HR salary cap.

Occupation	Percent Below Market
Veterinary Medical Officer	65%
Medical Officer	46%
Mathematical Statistician	41%
Operations Research	35%
Pharmacist	35%
Chemist	33%
General Biological Sciences	32%
Consumer Safety	28%
Toxicologist	26%
Microbiology	22%

The Agency has challenges in attracting highly motivated scientific and medical specialists who have an interest in taking on management and leadership roles when joining FDA. At the same time, some supervisors who excel within their technical specialty find, after a time, that they do not enjoy serving as supervisors for a variety of reasons and would like to relinquish that role. Lack of job satisfaction, coupled with inadequate salaries, has created a difficult situation for the Agency and exacerbated already existing hiring challenges.

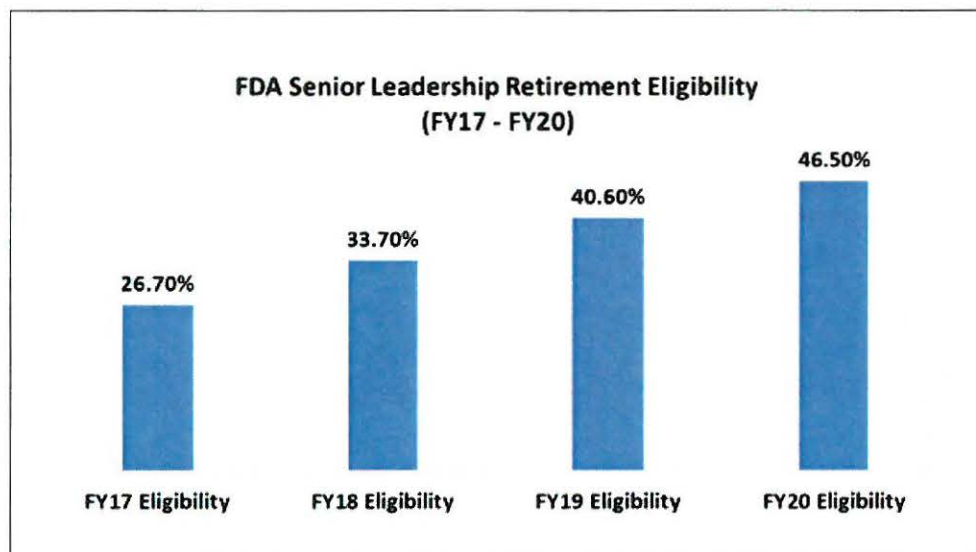
Attrition

Finally, FDA’s workforce needs are affected by staff attrition. Many employees find FDA a satisfying and enjoyable place to work, as evidenced by the fact that, when asked, FDA

employees overall have a high “intent to stay” (75.5 percent).³ Of employees in medical product Centers who do intend to leave in the next year, only between 2 and 8 percent of those said they plan to leave for a job outside of the federal government.⁴ Some 50 percent of employees at FDA remain at the Agency between 3.5 years to 4.5 years past their retirement eligibility date. While the overall picture appears favorable, FDA does have reason to be concerned about attrition.

In 3 years—by Fiscal Year 2021 (FY 21)—approximately 50 percent of the current senior FDA leadership will be eligible to retire. FDA is taking steps now to prepare a diverse group of future leaders to ensure that critical knowledge and expertise are not lost. Several organizational components are in a moderate- or high-risk status because 30 percent or more of the senior leaders (executive level and General Schedule (GS)-15) became eligible to retire as of September 30, 2017. Staff at the GS-15 level represent those who are logically next in line to fill executive vacancies.

From a sheer quantity perspective, new staff are needed across FDA to fill vacancies for new positions. While turnover at FDA is consistent with other federal agencies (approximately 5 percent a year), it may grow, given that 13.3 percent of staff were eligible for retirement in 2017. FDA data shows that almost half of senior leaders will be eligible for retirement by FY20 (see chart below). This data shows that, absent any other factors affecting the ability to recruit and retain staff, the Agency will need to continue filling important positions vacated through attrition throughout its components.



³ 2017 Federal Employee Viewpoint Survey data.

⁴ Ibid.

Patchwork of Authorities

To recruit and retain top talent, FDA has been using a patchwork of hiring authorities that either provide hiring flexibility, the ability to offer higher salaries, or both. While it has been helpful to have these other authorities (described on page 17) to attract talented individuals to FDA, those authorities have presented challenges. The Cures HR authority has been tailored specifically to FDA's needs, and will improve the Agency's ability to hire and retain the highly qualified staff needed to carry out its important work.

Strategic Plan for Recruitment and Retention at FDA

The Cures HR provisions gave FDA discretion to create a program that fits the unique human capital needs of a modern, science-based, regulatory public health agency; Cures also required a report on implementation of those provisions. FDA has embarked on an ambitious effort to improve recruitment and retention across the Agency, carefully implementing the new Cures HR authority, strategically using existing recruitment and retention strategies, and improving existing HR processes and procedures. While past efforts have often been led by individual Agency components, FDA is adopting a more strategic, enterprise-wide approach to establish recruitment and retention priorities.

Improving FDA's Overall Hiring Process

Spurred by the opportunity presented by Cures and the President's Management Agenda to streamline the federal government's business practices, FDA is undertaking an initiative to improve the overall hiring process across the Agency. The foundation of this initiative is the FDA Strategic Human Capital Plan, which establishes a comprehensive framework of human capital policies, programs, and practices to achieve FDA's goals. Under this plan, FDA is taking a systematic approach to evaluating and improving its HR enterprise to ensure that the Agency secures the qualified workforce necessary to meet the Agency's evolving responsibilities. FDA is compiling data on important factors such as changes in the Agency's mission-critical work, significant workforce skills gaps, programs with insufficient staff resources, and opportunities missed due to a lack of appropriately trained or sufficient staff. This data will be used to establish recruitment and retention goals that align with Agency strategic priorities and will help close projected employee gaps. The plan also establishes metrics to evaluate the Agency's progress in meeting these goals.

FDA published [*Initial Assessment of FDA Hiring and Retention – A Path Forward*](#) in November 2017, outlining findings and recommendations for improving FDA's hiring system. From this assessment came the FDA Hiring Initiative to reimagine the hiring process. One of the Initiative's components is a hiring pilot that will focus on filling 140 vacancies in CDER and CBER. As lessons are learned from the pilot, they will be implemented throughout the rest of the Agency.

Other Initiative activities underway include:

- Creating a new scientific staffing team to conduct outreach and candidate identification for hard-to-fill scientific jobs;
- Implementing an electronic classification system to streamline and expedite the administrative process and improve communications between the human capital team and hiring managers;
- Implementing new processes and procedures to significantly reduce the time to hire, ideally within 80 days;

- Launching a tracking and reporting system with added data quality measures to improve workflow; and
- Instituting new training requirements and other practices to improve Office of Human Resources staff performance.

Significant initiatives such as this take time; however, Agency officials believe that these efforts will begin to show measurable results in the near future.

Implementation of Cures HR Authority

The 21st Century Cures Act authorized the FDA Commissioner to hire individuals into certain positions without regard to typical civil service hiring requirements and salary caps (See 21 U.S.C. 379d-3a). The statute provides the following:

"(a) IN GENERAL .-The Secretary may, notwithstanding title 5, United States Code, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Such positions shall be within the competitive service.

(b) COMPENSATION.-

"(1) IN GENERAL.-Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Commissioner of Food and Drugs may determine and set-

"(A) the annual rate of pay of any individual appointed under subsection (a); and

"(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before the date of enactment of the 21st Century Cures Act.

"(2) LIMITATION.-The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

FDA has approached implementation of these flexible hiring and compensation authorities in a deliberative way, mindful of the importance of implementing the provisions carefully, equitably, and in a financially responsible way. Shortly after enactment of the Cures Act, FDA created a governance structure that included an internal HR Cures Working Group and an HR Cures Steering Committee chaired by the Commissioner, with representatives from all the FDA Centers and Offices, to begin implementing these new hiring flexibilities. FDA leadership works collaboratively with HHS leadership and regularly briefs the department on FDA's implementation progress.

FDA is using the authority in Cures to develop an Alternative Pay Structure (APS) that will balance the flexibility provided by Cures with policies and procedures to facilitate consistency. The Working Group thoroughly examined how APSs work throughout the federal government and private industry to understand best practices and lessons learned. The Agency also reviewed data comparing FDA salaries with appropriate counterparts in the private sector to fully understand the scope of the disparities. Based on extensive research and deliberations, FDA has adopted a phased approach to implementation of the Cures HR authorities. This phased approach will allow FDA to target the most critical positions first and to refine policies and procedures over time.

FDA's initial step in designing the new APS was to determine which positions at the Agency would be included within the statutory parameters of "scientific, technical, or professional positions that support the development, review, and regulation of medical products." Using the Office of Personnel Management (OPM) classification as a guide, FDA identified 38 such occupations. FDA then developed a pay structure, based in part on the GS scale, that includes nine bands. The Agency is in the process of completing policies and procedures to guide the placement of employees within these bands based on the type and relative complexity of different positions. The band structure, and accompanying policies, will facilitate consistency within individual Centers and across FDA.

Phase 1 of implementation of the Cures HR authority focuses on executive and supervisory positions within those 38 occupations, and within those Centers—CDER, CBER, CDRH, and the Center for Veterinary Medicine (CVM)—that provide most of the Agency's efforts to "support the development, review, and regulation of medical products." As noted in the Workforce Needs section, benchmarking research has shown that supervisory positions at FDA are particularly challenging to fill, and salaries are out of line with market rates. The next phase of implementation will focus on mission-critical positions that have historically been difficult to fill, and where FDA research has identified disparities between FDA salaries and market rates. FDA made its first two hires using Cures in early 2018, and expects additional hires in the coming months. FDA believes that, over time, the Cures HR authority will enable FDA to hire the new scientists, physicians, and other professionals it needs and to retain its current outstanding staff in order to accomplish its public health mission. With the Cures HR authority tailored to FDA's workforce needs, the Agency now has the flexibility to build an effective hiring and pay structure to support and augment its 21st century workforce.

Additional Recruiting Efforts

A strategic FDA-wide approach to recruiting is an important innovation in FDA's hiring process, enabling the Agency to fill multiple vacancies for the same job series across Centers by posting a single vacancy notice. This approach is referred to as "corporate recruiting." Although further refinements and improvements will be made, a wide range of job series is included in the corporate recruiting model to onboard new hires, and more are planned. FDA has created an Agency-wide scientific recruitment team to focus on outreach and talent identification to fill critical Agency positions.

Corporate recruiting establishes a process designed to announce commonly filled mission-critical positions across an organization on a recurring basis to provide managers with access to qualified candidates on a predictable schedule. Key goals of FDA's corporate recruitment strategy are to reduce the time to hire and streamline administrative procedures. Since 2015, when FDA began this effort, it has launched targeted recruitment strategies for specific occupations (e.g., mathematical statisticians, pharmacologists, toxicologists, chemists, pharmacists) and has successfully used this process to fill positions in these hard-to-fill professions. FDA is currently working on the next round of announcements for each of these five series, and new lists of qualified candidates were made available for each series in early 2018.

In addition to the significant HR process improvements underway, FDA is using a variety of tools to attract and retain the world-class workforce needed to carry out its public health responsibilities. A description of these efforts follows.

Use of Placement Agencies

FDA utilizes contractor resources to provide qualified executive-level or senior-level clinical and non-clinical candidates across the enterprise. This support is necessary to fill current critical executive and senior-level vacancies, maintain office efficiency and accountability, and prevent lapses when those employees retire or resign. In FY15, the Strategic Sourcing Initiative was established to fill highly specialized or managerial positions using new or novel recruitment methods to attract highly qualified candidates for open positions. In August 2015, FDA awarded the first Agency-wide executive recruiting services contract to a reputable and experienced firm, thereby expanding the use of professional recruiters for highly specialized and managerial level positions. The contract is helping FDA in search, recruitment, pre-screening, placement, succession and project management for clinical and non-clinical, and Senior Executive Service (SES), as well as under the hiring authorities commonly known as, Title 42(f) (42 U.S.C. 209(f); Title 38 (38 U.S.C. 7431), and Senior Biological Research and Biomedical Product Assessment Service (SBRS) (42 U.S.C. 237) positions.

Recruitment through Academic Institutions

FDA supports student and fellowship programs that are vital to the strategic recruitment of the Agency's workforce. For example, the two-year Commissioner's Fellowship Program has graduated 192 fellows since 2008, and 76 percent remained at the Agency. Additionally, the FDA – National Cancer Institute Interagency Oncology Task Force Fellowship has retained 49 percent of the fellows who have trained at FDA.

To support recruitment, FDA, working through its Centers, also conducts outreach to fill positions in science, technology, engineering, and mathematics (STEM) by participating in career fairs such as the Sixth Annual STEM Forum on Capitol Hill, the National Cancer Institute Career Fair, and science conferences such as the U.S. Science and Engineering Festival and the American Association for the Advancement of Science Conference. FDA also hosts 10 to 12 academic visits annually for students and fellows. FDA is actively participating in the Federal Strategic STEM Plan to attract scientists and related mission-critical professionals to FDA.

FDA also conducts on-campus scientific recruiting events (e.g., Johns Hopkins University, George Washington University, University of Maryland). The Agency has established ongoing strategic relationships with many academic institutions and professional associations so that when FDA is conducting its corporate recruitment, it can readily advertise Agency positions to those institutions when vacancies arise. Examples of outreach conducted in 2018 include activities at meetings of the American Public Health Association, the American Society for Clinical Oncology, the Joint Statistical Meetings, and the Drug Information Association. In addition, FDA trains staff who attend these meetings so they can function as employee ambassadors for FDA, helping identify and recruit qualified candidates.

Academic Programs

Undergraduate and Graduate Student Programs

- Device Evaluation Intern Program
- Veterinary Clerkship Program
- Federal Information Privacy Internship Program
- Interdisciplinary Toxicology Program
- Student Internship Program
- Medical Device Fellowship Internship Program
- OCE Summer Scholars Program
- Office of Policy Internship
- Oak Ridge Institute for Science and Education (ORISE) Research Program
- Pharmacy Student Experiential Program
- Science Internship Program
- Student Volunteer Service Program
- Summer Student Research Program
- Veterinary Clerkship Program
- Visiting Pediatric Pharmacology Fellows Rotation Program

Fellowships for Post-Graduates

- Commissioner's Fellowship Program
- Inter-Agency Oncology Task Force Joint Fellowship Program
- Medical Device Fellowship Program
- Pathways Program for Recent Graduates
- Post-graduate Research Program
- Regulatory Pharmaceutical Fellowship
- Service Fellowship Plan
- Tobacco Regulatory Science Fellowship

Hiring Bonuses (Recruiting Incentives)

FDA has recently increased its use of recruitment incentives, specifically for hard-to-fill positions such as mathematical statisticians. To use such bonuses, Centers determine difficult-to-fill positions and document the expertise and unusually high or unique qualifications of the employee. Employees who accept a bonus must sign a written service agreement to complete a specified period of employment with the Agency (not less than 12 months nor more than 4 years). Such bonuses have been used in a targeted manner to attract highly qualified candidates for several hard-to-fill positions.

Direct Hire Authority

Direct Hire Authority (DHA) is an appointing (hiring) authority that OPM can give to federal agencies to fill vacancies when a critical hiring need or severe shortage of candidates exists. DHA allows an agency to hire more rapidly using streamlined procedures. FDA uses the government-wide DHA to fill physician, pharmacist, nurse, veterinary medical officer, and information technology management (information security) positions. FDA, through HHS, can seek its own DHA for any positions deemed to have a critical hiring need or a severe shortage of candidates. For example, FDA established a dedicated team to expedite the hiring of physicians using DHA. The team manages a streamlined 10-day hiring process from package submission to tentative offer. This is valuable authority given the central importance of clinical staff in much of FDA's mission-critical work.

Other Pay Authorities

Most FDA employees (81.9 percent) are paid according to the GS scale. FDA has access to other authorities that enhance FDA's ability to recruit and retain staff.

- **U.S. Public Health Service Commissioned Corps:** Provides positions for highly trained public health professionals including physicians, dentists, nurse practitioners, and other specialists. The Commissioned Corps is overseen by the Surgeon General.
- **Title 42 (g):** Provides fellowships for the employment and development of promising research and regulatory review scientists. Candidates must have a Ph.D. or equivalent degree (e.g., Medical Doctor (MD), Doctor of Veterinary Medicine (DVM), or Doctor of Science (D.Sc.)). The salary ranges from a GS-7 to GS-15. See 42 U.S.C. 209(g).
- **Title 42 (f):** Provides the authority to hire "special consultants" engaged in the performance of scientific work. These are scientific management positions with salaries up to \$400,000, though HHS approval is needed for any salaries higher than \$275,000. See 42 U.S.C. 209(f).
- **Title 38:** Used to attract, compensate, and retain Physicians (0602 series) and Dentists (0680 series). OPM Delegation of Agreement with HHS allows FDA the ability to use the Department of Veterans Affairs Title 38 Pay Tables to set pay for FDA physicians

Pay Plan Type	%
General Schedule	81.9%
Commissioned Corps	6.6%
Title 42 (g)	5.4%
Title 38	4.4%
Title 42 (f)	0.9%
SES	0.4%
SBRS	0.3%

and dentists who provide services incidental to or directly related to clinical/patient care and possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a Territory of the United States. Pay can be set up to \$400,000 dependent upon specialty, but must be approved by HHS. FDA has the authority to approve pay up to \$275,000. See 38 U.S.C. 7431.

- **Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service:** As currently implemented, SBRS allows FDA to recruit and retain scientific and technical experts in the fields of biomedical research and clinical research evaluation. Staff in SBRS positions must demonstrate that they are qualified and outstanding in their fields. Salaries may go up to \$210,700. Once amendments made by Cures are fully implemented, the program will include experts in biomedical product assessment and required credentials will expand to include those with doctoral- or master's-level degrees in engineering, bioinformatics, or a related or emerging field. Salaries may go up to \$400,000. See 42 U.S.C. 237.

Although not created to meet FDA's specific hiring and retention needs, these authorities nonetheless afford FDA valuable flexibility in hiring and setting pay.

Pathways Program

FDA is working to expand its talent pipeline by leveraging special appointment authorities under OPM's Pathways Program. The Pathways program has three components, which consist of the Internship program, the Recent Graduates program, and the Presidential Management Fellows (PMF) program. The PMF program is a premier 2-year leadership training program for graduates of an advanced degree program. Over the past 3 years, FDA hired 14 employees through the PMF program, which helped to fill mission-critical gaps and is helping create a new younger cadre of future leaders who will be prepared for added responsibility as FDA's retirement eligible workforce prepares to leave. FDA will continue to utilize the Pathways Program to develop a diverse talent pipeline while also better leveraging the Student Volunteer Employment Program to build a robust and diverse group of students and graduates.

Social Media Strategy

FDA has consolidated its social media platform to increase its digital presence for recruitment. In addition, the Agency is working to improve its strategic outreach and recruitment efforts by leveraging multiple technologies, including expanded use of digital media, such as LinkedIn, to actively identify promising candidates for hard-to-fill and critical positions and improving the recruitment content on the FDA website.

Retention Efforts

Once employees have been recruited to the Agency, FDA makes significant efforts to retain them. The compensation flexibility provided under the Cures Act, as well as the existing hiring

and compensation authorities, including SBRS, will be important in retaining FDA's current highly experienced, valuable employees.

While competitive and equitable salaries and retention bonuses are certainly important for retention, FDA makes a variety of efforts to enhance its work culture and environment to make the Agency an attractive place to pursue a career.

Work-life balance initiatives include telework and alternative work schedules (AWS). In 2017, 46.8 percent of FDA FEVS respondents indicated they telework between 1-2 days per week, and 13.4 percent indicated they telework 3 or more days per week. The survey also found 34.7 percent of respondents participate in the AWS Program. Other important retention efforts are discussed below.

The FDA Employee Value Proposition

Employee Value Proposition (EVP) is a term used to convey the balance of rewards and benefits that employees receive in return for their performance in the workplace. An EVP is a simple, overarching statement that communicates an employer's brand and commitment to its employees. It encompasses the entire employee work "experience" from offerings provided by an organization—including rewards and benefits and opportunities for career development—to the organization's management style, work environment, and culture. The EVP serves to define how the organization would like to be recognized as an employer and defines the "give and get" of the employment relationship.

Increasingly, organizations are working to define their EVP to enhance their talent management programs and processes. Research indicates that organizations that use their EVP most effectively are five times more likely to report their employees are highly engaged and twice as likely to report achieving financial performance significantly above their peers compared to organizations that use their EVP less effectively.⁵ FDA plans to integrate an EVP into its recruitment and retention initiatives. It may take some time to see the benefits of using the EVP, but there is supporting evidence that it will help retain employees.

Diversity and Inclusion

FDA is committed to building on its current strengths by continuing to cultivate a highly diverse and inclusive environment. The Diversity and Inclusion Steering Council, comprising executive leaders from each Center and the Office of the Commissioner, reviewed the diversity and inclusion goals used by OPM, other federal agencies, the Centers, and FDA's own diversity and inclusion goals to establish FDA's new goals for FYs 18–21. FDA staff led the effort to establish the priorities, implementation strategies, and actions to accomplish the goals. The combined efforts of each Center and office to fulfill these goals are increasing attention to diversity and support FDA's inclusion and engagement efforts.

⁵ Towers Watson (2014). "Build a Compelling Employee Value Proposition." <https://www.towerswatson.com/en/Insights/Newsletters/Europe/HR-matters/2014/01/Build-a-compelling-employee-value-proposition>

FDA continues to make great strides in creating a robust FDA diversity and inclusion program. Important activities include the following:

- Ensuring that employees throughout the Agency, especially new managers and supervisors, complete diversity management training;
- Focusing on under-represented populations in the workforce and sharing recruitment materials with those groups to help ensure the workforce represents those the Agency serves;
- Sponsoring diversity events and commemorative programs across the Agency to raise diversity awareness; and,
- Continuing to build on partnerships with FDA’s Employee Resource Groups and affinity groups through employee gatherings and job fairs.

Additionally, the Agency is developing a web-based workforce analytics tool that will assist with tracking diversity trends and identifying under-representation to better inform targeted outreach and recruitment activities.

Succession Planning

Succession planning is intended to identify and prepare high-potential candidates who can replace individuals in critical roles in an organization. It increases the availability of experienced and capable people who are prepared to advance and take on new roles in an organization when former leaders leave. Succession planning reduces the leadership “vacuum” and ensures a smooth transition and continuation of operations through training, leadership development, and knowledge management.

FDA is developing workforce and succession planning strategies to help the Agency become proactive in identifying projected workforce gaps to reduce the need for reactive hiring. The Agency annually reviews data that highlight how effectively FDA and its Centers recruit and retain mission-critical occupations. The Agency has begun building a framework to identify gaps and improve FDA’s leadership strength. A knowledgeable workforce with skilled senior leadership is critical to achieving the FDA mission. Accordingly, the Agency needs well-formulated plans to meet its succession challenges. It is estimated that in 5 years, approximately 50 percent of the current senior leadership will be eligible to retire. FDA will need to determine the best way to fill mission-critical senior leadership positions.

To address these issues, FDA is developing succession management strategies that will shape FDA’s future leadership cadre. FDA is improving its strategic human capital practices; continuing to promote an inclusive and fair work environment; and developing a talented, diverse, and engaged executive cadre needed to fulfill its mission.

Leadership Development and Training Offerings

To retain its highly qualified workforce, FDA invests in and emphasizes career development at all levels within the organization. Since 2014, the Agency has offered leadership and career development and training programs including:

- Leading at All Levels, a course for individual contributors (GS-7-12)
- Leading for Results, a course for mid-career staff (GS-13-14)
- The FDA Leadership Development Program, a competitive program for GS-14 and 15s

These offerings have been popular with staff, with participants indicating that they were better prepared for new leadership opportunities. Leadership development in general leads to greater job satisfaction, and FDA is committed to continuing these offerings.

Commissioner's Recommendations

The Cures HR hiring authority came at a critical time in the history of FDA and our ability to help advance promising new medical science. These new authorities will help ensure that FDA is equipped to fulfill our critical public health mission and promote these opportunities.

As noted in this report, FDA's statutory responsibilities and authorities have grown considerably over the past decade. In recent years, we have seen the implementation of the most significant food safety reform in our nation's history, the passage of the Family Smoking Prevention and Tobacco Control Act, and most recently the passage of the Cures Act and FDARA.

Our people are critical to this mission. Our increasing obligations and authority requires FDA to recruit and retain a strong, committed, and talented workforce. Every day, FDA's professional staff leverages the rapid advances in science to offer patients more opportunities to improve their health, while also taking advantage of these same innovations to make sure the products people use are safe. But our hiring practices and authorities have not kept pace with our congressional mandates.

The two hiring provisions included in Cures reflect the focus and support by Congress on these challenges and opportunities, as well as an appreciation that the strength of FDA is its people. The provisions are recognition of the importance of hiring and retaining highly skilled experts. FDA is committed to maintaining the tools and resources to recruit and retain a highly qualified and dedicated workforce. This is a key to our ability to fulfill our goals to protect and promote the public health and execute our responsibilities and obligations as set out by Congress.

It is well known that FDA has had challenges recruiting and hiring. This is, in large measure, due to the cumbersome patchwork of hiring authorities that were not designed specifically for FDA. The existing patchwork of hiring authorities created inconsistencies across positions and centers, and hiring challenges and inefficiencies across the entire FDA.

The Cures hiring authority was drafted specifically to meet the unique needs of FDA and addresses many of the hiring challenges we are facing. It specifically addresses those staff in scientific, technical, and professional positions whose work supports the development, review, and regulation of medical products. However, this focus may not fully address other hiring needs across FDA. The Agency is committed to working further on these challenges.

Because of FDA's organizational structure, there are positions (such as that of statistician) where individuals can perform similar work across the Agency's different Centers and yet, depending on whether or not they are in a Center or office that supports the development, review, and regulation of medical products, these individuals may not be eligible for the Cures authority. This would put them in a different pay structure than a person with similar skills and responsibilities who might be situated in a different FDA Center. For example, a statistician working in the Center for Tobacco Products (CTP) or the Center for Food Safety and Applied Nutrition (CFSAN) could not be hired through this authority or be eligible for the new pay scale. As a result, these Centers and related offices could be disadvantaged.

FDA hopes to explore ways to ensure that all our hiring needs and obligations are met across the Agency. As described in the report, over the last year, FDA has worked hard to carefully implement the Cures hiring authority. We are already beginning to see the benefits to the Agency, and we look forward to continuing to use this important authority for important scientific, technical, and professional positions that support the development, review, and regulation of medical products. Given the improvement that we expect these hiring flexibilities to make in our ability to recruit and retain a world-class workforce, our experience to date suggests that similar authority may be useful at some time in the future to support vital functions in FDA components carrying out other aspects of the Agency's mission.

Flexible hiring authorities empower supervisors to recognize high-quality work and provide Center Directors with the means and authorities to staff their Centers appropriately for advancing regulatory science and meeting user-fee goals. Our goal is a payment system across all of FDA that allows for pay parity, so that we will be able to retain and reward valuable employees.

FDA will use hiring flexibilities judiciously. As we begin to implement the new authority, we plan to apply the highest pay band to the most senior positions, and for uniquely critical scientific hires. Our budget cannot support an overly broad adoption of these pay scales, however, and so we will continue to be conservative in how we apply these tools.

The strength and capacity of the FDA turns first and foremost on the caliber of our people. Examining ways to expand this critical authority is one of my top priorities to ensure that the FDA fulfills our critical public health mission. The Agency welcomes an opportunity to continue to work with Congress to discuss and address FDA's hiring authorities.