

# GAO Highlights

Highlights of [GAO-22-104791](#), a report to congressional committees

## 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](mailto:dickenj@gao.gov).

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## 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 | ●                                                   |
| Monitor and evaluate progress toward human capital goals       | ◐                                                   |
| Develop a strategic workforce plan                             | ○                                                   |

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.