

441 G St. N.W.
Washington, DC 20548

Accessible Version

May 8, 2020

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

Biomedical Research: HHS Has Not Yet Used New Authorities to Improve Recruitment and Retention of Scientists

The Department of Health and Human Services (HHS) has cited difficulties in recruiting and retaining individuals in medicine, science, engineering, and other related fields to support its mission. Since 2001, 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 are undermining agencies' abilities to meet their missions.¹

The recruitment and retention challenges we have identified at HHS affect its agencies, such as the National Institutes of Health (NIH), the nation's leading biomedical research agency. As such, the agency must rely, in part, on an expert staff of biomedical scientists to conduct research in various areas such as biological, biomedical, behavioral, and health sciences, in NIH laboratories and clinics. To that end, NIH's success depends on the agency's ability to attract and retain a national biomedical workforce. In 2018, the Director of NIH testified that the agency has been concerned about the long-term stability of biomedical research for many years.² In that testimony, the Director noted that researchers must compete for limited resources, thereby creating a challenging environment for new and mid-career scientists.

¹U.S. Government Accountability Office, *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP (Washington, D.C.: March 2019).

²Testimony from Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health, U.S. Department of Health and Human Services on 21st Century Cures Implementation: Updates from FDA and NIH before Committee on Energy and Commerce, Subcommittee on Health, July 25, 2018. Downloaded from <https://www.hhs.gov/about/agencies/asl/testimony/2018-07/implementing-21st-century-cures-act-collins.html>, accessed March 26, 2020.

Like NIH, HHS's Food and Drug Administration (FDA) officials have also expressed difficulty competing with private industry to recruit senior scientists. FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, food, cosmetics, and products that emit radiation, as well as advancing public health. A 2015 report from the FDA Science Board noted challenges related to salaries, among other things.³ For example, the report noted that well-paid physicians in the private-sector may be willing to work at FDA, but not when FDA can only pay them about 25 percent of their current pay. As a result, the report states, many eligible and desirable candidates do not apply for positions at FDA, nor are willing to take the financial loss associated with those positions. This challenge continues, according to FDA and another stakeholder. In particular, an FDA report also noted that the 14 percent job vacancy rate at two of its centers in fiscal year 2017 was higher than the 5 to 7 percent vacancy rate at other government agencies.⁴ In 2017, The Milken Institute reported that FDA has substantial staffing shortfalls, with more scientists going to the private sector, where the salaries are higher, than to government positions.⁵

One mechanism available to help address these recruitment and retention challenges is the Senior Biomedical Research Service (SBRS) which was established in 1996 under section 228 of the Public Health Service Act (PHSA) to recruit and retain outstanding research scientists (referred to as "members") of the SBRS.⁶ The pay for members of the SBRS is up to Level I of the Executive Schedule, which in 2020 is \$219,200, which is higher than generally allowed for government scientists.⁷ Positions at the SBRS are reserved for individuals actively engaged in either peer-reviewed original biomedical research or clinical research evaluation. To be eligible for the SBRS, an individual is required to have a doctoral degree in biomedicine or a related field. Biomedical research is the study of the biological process and causes of disease, including the prevention and treatment of disease as well as both genetic and environmental factors related to disease and health. Biomedical research has been conducted in areas such as HIV, influenza, cancer, and the virus that causes the Coronavirus Disease 2019 (COVID-19).

To provide additional hiring and retention authority to HHS, the 21st Century Cures Act (enacted in December 2016) made several amendments to section 228 of the PHSA, including renaming the SBRS as the Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (the Service).⁸ Specifically, these amendments also established new authorities related to recruitment and retention: increasing the number of authorized members of the Service from 500 to 2,000, authorizing the appointment of persons who hold a master's degree in engineering, bioinformatics, or related or emerging fields (previously only those with doctoral degrees were eligible), and increasing the top pay for members from \$219,200 in 2020

³Science Looking Forward Subcommittee of the FDA Science Board, *Mission Possible: How FDA Can Move at the Speed of Science*. (September 2015).

⁴Food and Drug Administration, *Initial Assessment of FDA Hiring and Retention—A Path Forward*. (November 2017).

⁵The Milken Institute, *Strengthening FDA's Workforce: Opportunities for Action*. (March 2017)

⁶Codified at 42 U.S.C. § 237; See 61 Fed. Reg. 6556, 6557 (Feb. 21, 1996) (codified at 42 C.F.R. pt. 24).

⁷For 2020, the federal pay in the Washington, DC area, for example, is \$170,800 or lower. Federal employees have different pay scales to compensate for the costs of living in various parts of the country.

⁸Pub. L. No. 114-225, § 3071(a), 130 Stat. 1033, 1133 (codified at 42 U.S.C. § 237).

to an amount consistent with the President's salary (currently \$400,000 per year), among other changes.

The Act also included a provision that we report on the extent to which the recruitment and retention of biomedical research scientists and those in related fields at HHS has been affected by these amendments. In this report, we describe HHS's efforts to implement the recruitment and retention authorities of the Silvio O. Conte Senior Biomedical Research Biomedical Product Assessment Service.⁹

To describe HHS's efforts to implement the recruitment and retention authorities of the Service, we reviewed documentation about the SBRS and the Service. We also interviewed departmental officials at HHS, as well as agency officials at NIH and FDA since those agencies were prominent users of SBRS and can be expected to be prominent users of the Service.

We conducted this performance audit from December 2019 to May 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

HHS Has Issued Regulations But Not Yet Begun to Use New Authorities for Recruiting and Retaining Biomedical Research Scientists

On April 20, 2020, HHS issued regulations to guide implementation of the recruitment and retention authorities provided by the 21st Century Cures Act for the Service.¹⁰ HHS officials told us that they worked with relevant HHS agencies to draft these regulations. The officials said that the HHS agencies that are expected to use the Service authorities for recruitment and retention are NIH, FDA, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality. According to HHS officials, the department is preparing guidance based on discussions with its agencies for the allocation of specific membership slots for each agency for recruitment and retention. NIH and FDA officials told us that after they receive their membership slots, they would begin their recruitment and retention process. FDA officials said that process could take up to 6 months until members are selected.

Agency Comments

We provided a draft copy of the correspondence to HHS for review and comment. HHS 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 <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or deniganmacauleym@gao.gov. Contact points for our Offices of Congressional

⁹Pub. L. No. 114-255, § 3071(b), 130 Stat. 1134.

¹⁰85 Fed. Reg. 21780, 21781 (Apr. 20, 2020) (revising 42 C.F.R. pt. 24).

Relations and Public Affairs may be found on the last page of this report. Other key contributors to this report include Karen Doran (Assistant Director), Carolyn Feis Korman (Analyst-in-Charge), Sam Amrhein, and George Bogart.

A handwritten signature in black ink, appearing to read "Mary Denigan-Macauley".

Mary Denigan-Macauley
Director, Health Care

(Job code 104008)