Strengthening FDA's Workforce: Opportunities for Action

The work of the U.S. Food and Drug Administration (FDA) is central to the health and well-being of all Americans. The agency regulates 20 cents out of every $1 spent by consumers[1] – including the entire spectrum of medical products, from drugs to surgical robots to mobile medical apps. There has been a growing drumbeat of concern – starting with the FDA Science Board's "FDA Science and Mission at Risk" report in 2007 – over the agency's persistent challenges to building and maintaining its workforce of highly trained scientists, clinicians and engineers. However, there are opportunities to curb further erosion of FDA's ability to meet its mission.

FDA is like a basketball team with only four players on the court.

- The Center for Drug Evaluation and Research (CDER) has more than 700 vacancies, representing a 13 percent reduction in force.[2] The other medical product review centers face similar workforce shortfalls.
- FDA staff are dedicated and meet the vast majority of drug and device review performance goals, but at what cost to morale and the agency's mission? Given the pressures to meet performance goals, the vacancies force agency leaders to make tough choices between product reviews and broader initiatives, such as advancing regulatory science and developing guidance documents.

Public service is a powerful motivator for FDA employees, but industry competition for staff is fierce.

- FDA staff are proud of the work they do and the environment in which they work.
    - Based on employee survey results, the Partnership for Public Service's "Best Places to Work in the Federal Government" 2016 report ranked FDA as the second best public health agency to work at.[3]
- But there is a limited pool of specialized scientific staff from which FDA and industry are recruiting.
    - For example, biostatisticians are crucial components in the industry teams that develop clinical trials and the FDA teams that review those trials. In 2014, there were just 167 biostatistics doctoral degrees conferred in the United States. Industry hired 44 percent of them, while government could only attract 6 percent (the rest stayed in academia).[4]
- And there is a significant imbalance between government and industry compensation.
    - FDA's top 100 senior staff (0.6 percent), among the most highly trained and educated employees in government, had salaries averaging $251,000 in 2014.[5] (The average FDA salary was $106,137.[6]) Most staff live and work in the Washington, DC area, which has one of the highest costs of living in the country.
    - In the same period, industry vice presidents with regulatory responsibilities averaged $320,570, with the top 10 percent averaging $472,500. The top 0.6 percent would undoubtedly earn far more.[7]

Federal human resource (HR) practices and other policies further hinder FDA's ability to effectively compete for staff.

- In 2012, FDA's HR functions were moved back to FDA from a centralized Health and Human Services (HHS) office to better serve the unique needs of the agency. It has been reported that HHS still influences FDA hiring policies.[8]
    - For example, the FDA Science Board's 2015 "Mission Possible: How FDA can move at the speed of science" report found that HHS limited FDA's use of the flexible Title 42, which allows for special, higher pay authorities for scientific experts.
- One-quarter of FDA's posted vacancies are not filled during the open window because federal HR systems are not optimized for the highly specialized skills and experience FDA requires. Because of the overwhelming number of applications that come in via the USAjobs.gov website, it is difficult to locate and sift out the best candidates with the necessary technical and scientific skills.
    - These searches require three to four months to be revised and reissued, prolonging FDA's staffing shortage and increasing the odds that a candidate will go elsewhere.[9]

- High performers are not rewarded via compensation.
    - Another finding stated in the "Mission Possible" report, "FDA has no mechanism to give outstanding scientists meaningful bonuses or merit increases in their salaries." Additionally, "Even when permitted, annual performance awards and merit increases are not competitive with the private sector."
- Staff travel to scientific conferences and technical training is essential to FDA's mission, yet travel was curtailed in 2012 by Office of Management and Budget (OMB) memorandum M-12-12 mandating 30 percent cuts to travel budgets in all federal agencies. Participation in scientific meetings is critical to FDA's fluency in cutting-edge science.

Opportunities to innovate FDA's HR system are within reach.

- Realizing the promise of the 21st Century Cures Act's (P.L. 114-255) reforms to FDA hiring authorities would enhance the agency's ability to compete more effectively with industry for top talent.
    - FDA was granted a new direct-hire authority exempt from the provisions of Title 5 of the United States Code that govern most federal hiring. These hires would have their salaries capped at $400,000, the level of the president. (Sec. 3072)
    - The existing Senior Biomedical Research Service was reformed to widen the scope of eligible candidates, remove the HHS-wide hiring restriction (which capped the organization at 500 employees) and boost the salary cap to the level of the president. (Sec. 3071)
    - FDA staff travel to scientific conferences and technical training was exempted from the restrictions imposed by OMB memorandum M-12-12. (Sec. 3074)
- Empower FDA leaders to use this newly improved suite of authorities to more effectively recruit and retain key staff.
- Provide additional funding to support the competitive salaries enabled by these new hiring authorities.
    - FDA is a staff-intensive organization, not a granting agency like the National Institutes of Health. Eighty percent of its spending is on personnel-related costs.
- Provide unique job opportunities that can only be found in government.
    - For example, in June 2015, FDA's Office of Oncology and Hematology Products announced a partnership with the National Cancer Institute (NCI) to create three positions for mid-career medical oncologists who would design and run clinical trials at NCI and then participate in regulatory reviews at FDA.
- Explore ways to streamline conflict-of-interest (COI) policies for FDA staff – especially for experienced, mid-career candidates coming from industry.
    - As a regulatory agency, effective COI mitigation policies are critical. However, slow, cumbersome COI review during recruitment reduces the chances of a successful hire.
    - Opportunities to mitigate COI through Qualified Blind Trusts or Qualified Diversified Trusts should be explored.

All Americans rely on the medical products reviewed by the FDA. The agency's unique mission – coupled with a highly competitive environment for a small pool of specialized technical staff – makes it imperative that we improve FDA's HR authorities and policies so that the agency can continue to effectively accomplish its lifesaving work.

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[1] "Consumer expenditure on FDA regulated products: 20 cents of every dollar," FDA Voice, November 1, 2016.
[2] Vacancy figures are continually shifting; FDA provided this information in: "Despite ramped-up hiring, FDA continues to grapple with hundreds of vacancies," Washington Post, November 1, 2016.
[3] "Agency Rankings by Mission: Public Health," Best Places to Work 2016, Partnership for Public Service.
[4] "2014 Annual Survey of the Mathematical Sciences in the US," American Mathematical Society.
[5] www.FedsDataCenter.com, accessed November 11, 2015.
[6] "Justification of Estimates for Appropriations Committees," FDA, fiscal year 2016.
[7] "2014 Scope of Practice & Compensation Report for the Regulatory Profession," Regulatory Affairs Professionals Society.
[8] "The State of the FDA Workforce," Partnership for Public Service, November, 2012.
[9] Information provided by FDA staff at a meeting organized by the Alliance for a Stronger FDA, June 4, 2015.