FDA Response to the Science Board's Evaluation of the Commissioner's Fellowship Program

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Executive Summary

In June 2014, the Food and Drug Administration (FDA) charged the Agency's Science Board to evaluate the Commissioner's Fellowship Program (CFP). In July 2015, the Science Board Subcommittee presented its recommendations to FDA on a) funding the CFP, b) program goals, c) partnerships with universities, d) project and Fellow selection, e) program length and training, and f) evaluation.

FDA's CFP Advisory Board discussed the recommendations and determined that the CFP would be a more successful program by taking the following steps:

1. Targeting potential areas for staffing by increasing Center efforts to determine projected scientific needs when selecting projects and preceptors
2. Permitting senior scientists to apply by removing the seven years from degree eligibility requirement
3. Letting the project scientific needs determine the necessary knowledge and skills instead of requiring that all fellows have a doctoral degree
4. Allowing the scientific project to determine the time needed by granting extensions, to a maximum of four years in the program, with a 1. 5 year-residency requirement
5. Enabling more time for the scientific project by offering required training early in the program
6. Facilitating increased attendance at critical Center trainings by reducing CFP training to five required courses that focus on an overview of FDA and the Agency's policies and operations
7. Requesting 75% of the operating budget in the first two quarters of the fiscal year so that Fellows may begin or continue to conduct research

These CFP changes provide program flexibility to address the Agency's scientific needs; enable the program to train scientists for FDA; and enable FDA to contribute to the regulatory science workforce in academia and industry.

Introduction

In the autumn of 2008, FDA launched the Commissioner's Fellowship Program (CFP) with the goals of:

1. attracting top-tier scientists to FDA to address regulatory science issues through mentored, high-priority Agency projects
2. providing regulatory science training to these Fellows and
3. serving as a potential recruitment tool.

The three major CFP graduation requirements are:

1. completion of 11 required courses that emphasize core disciplinary needs and provide a solid base for understanding regulatory science
2. completion of a regulatory science project addressing a high-priority need under the mentorship of an established FDA scientist, and
3. substantive engagement in regulatory/review work.

Since 2010, there have been 208 graduates, with 76% (n=158) retained at FDA.

In June 2014, FDA charged the Science Board to conduct an evaluation of the CFP. After accepting the charge, the Science Board formed a subcommittee that reviewed background materials and conducted a site visit with CFP Fellows, Preceptors, and Preceptor Supervisors as well as FDA Center Directors and Advisory Board members. The Science Board provided the final evaluation in July of 2015.

Overall, the subcommittee found that the CFP is meeting its three goals. However, there are seven recommendations for a) funding the CFP, b) program goals, c) partnerships with universities, d) project and Fellow selection, e) program length and training and f) evaluation.

Changes to the Commissioner's Fellowship Program (CFP)

This document presents the planned changes to the CFP, informed by the FDA CFP Advisory Board's discussion of the Science Board's recommendations.

Funding the CFP

Currently, CFP funding is provided from the FDA Centers' budget, with the Office of the Chief Scientist (OCS) coordinating the funding each fiscal year. Given OCS's overall budget, it is not currently possible for the OCS to fully fund the CFP with this program as a stable line item in the OCS budget. The FDA Centers will continue to support the CFP

financially, with the OCS centrally coordinating the funding. The CFP program is working with the Centers so that 75% of the total fiscal year funding is available in the first two quarters of the fiscal year**,** which eliminates the undependable quarterly allotments. Although Reagan Udall Foundation (RUF) support is permissible under the Food, Drug and Cosmetic Act, the RUF does not have the funds or capacity currently to support the CFP.

Program Goals

FDA is maintaining the three original CFP goals, which it has successfully met, namely (1) attracting top-tier scientists to FDA to address regulatory science issues through mentored, high-priority Agency projects, (2) providing regulatory science training to these Fellows, and (3) serving as a potential recruitment tool.

FDA's hiring authority for the CFP is for federal employees. Although hiring and training scientists for industry and academia falls outside of FDA's hiring authority for CFP fellows, FDA does recognize that the CFP may have an impact on the development of Fellows who then go to academia and industry. Thus, FDA is reporting the number of Fellows who go to academia and industry and how these Fellows are using their CFP training in their new positions.

Partner with Universities to Include CFP as Experiential Component of Degree

The CFP is structured around a regulatory science project addressing a high-priority need, and FDA may be able to support student and post-doctoral rotations through the CFP if the experiential component meets the needs of the project requirements. Students may also obtain FDA experience through FDA student programs and the Agency has a number of post-graduate fellowships. FDA plans to increase promotion of all the Agency student and post-doctoral programs through outreach efforts to academia.

Project and Fellow Selection

Centers now identify a CFP project that is not always based on scientific priorities but they are increasing efforts to determine the projected scientific needs when selecting projects and preceptors. Because the scientific project may require advanced skills, the CFP is eliminating the "seven years from degree" eligibility requirement, which makes it possible for the Centers to select senior scientists. This is a desirable option since many of the other FDA fellowship programs are for scientists early in their career. Moreover,

the required doctoral degree is being removed to enable increased degree flexibility determined by the project needs.

Program Length and Training

The CFP is currently a two-year training program. Because the scientific project determines the duration, CFP is still requiring two years, with a residency requirement of 1.5 years in the program for a Fellow to be considered as a graduate. This new residency requirement discourages the Fellow from leaving the program early. To meet the scientific project's needs, the CPF is granting annual extensions for a maximum of four years in the program. The extension is determined by the preceptor and financially supported by the Center.

The CFP currently requires that a Fellow complete 11 courses that emphasize core disciplinary needs and provide a solid base for understanding regulatory science and FDA operations.

The CFP is decreasing the required training to five courses that focus on an overview of FDA and operations, giving preceptors and fellows more autonomy when selecting their learning opportunities from Center training as well as training through academic courses or certificate programs.

The CFP will continue to require three regulatory experiences, such as review of a product application, developing policy or guidance, attending regulatory meetings with industry, attending an advisory committee meeting, or attending an open, public hearing.

Additionally, to provide more time to devote to the scientific project, the required courses will be offered early in the program so the Fellow may focus on the CFP project requirements for the majority of the time in the program.

Retention

Commissioner's Fellows are hired under Title 42 209(g). This hiring authority permits temporary appointments and does not allow for conversion to a permanent position in the competitive service. Because of the hiring authority, CFP Fellows need to apply for positions at FDA. The CFP will continue to assist Fellows by making their information available to supervisors and providing assistance with employment questions. Moreover, lengthening the program gives Fellows more time to find a position at FDA.

Evaluation

The CFP does evaluate Fellows who remain at the Agency and it has requested the Office of Management and Budget's approval to survey Fellows who leave the Agency. For Fellows who do not remain at FDA the survey includes questions about how they are using the knowledge they acquired at FDA in their industry or academic position. The CFP is planning to conduct long-term follow-up of the CFP in 2017 and every five years thereafter.

III. Conclusions: The New CFP

Although the CFP has been successful in meeting the three program goals, several changes would enhance it. FDA is making several changes recommended by the Science Board such as changing the eligibility requirements and reducing required training; but dedicated centralized OCS funding and automatic conversion are currently not possible. Overall, changes in program length, applicant eligibility, and required training provide flexibility so that the Agency may address a variety of scientific priorities. Moreover, to facilitate the Agency's return on investment through the potential employment of Fellows, the Centers are increasing their efforts to identify scientific priority needs.

In summary, FDA is confident that the changes being made will improve the program, enabling the Agency to address scientific projects for regulatory challenges and groom scientists ready for FDA, industry, or academia.