

Scientific Engagement at FDA

Subcommittee Report to the FDA Science Board

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Scott Steele, PhD
University of Rochester

Background

FDA actively engages the external scientific community to advance the Agency's public health mission in several ways:

- PPPs can help advance FDA's mission by harnessing outside expertise to answer challenging scientific questions (e.g., cutting-edge medical products, food safety issues, etc.)
- Intramural research that FDA conducts provides a mechanism for engaging outside scientists at all stages of experience and training via fellowship programs
 - Fellowships are vital to developing the next generation of regulatory scientists and reviewers

Charge to the Subcommittee

Goal: FDA seeks input from the Science Board on how the Agency can improve its interface with the outside scientific community, including ways in which FDA can better focus and manage such efforts.

Questions:

- When is an FDA goal most appropriately addressed through participation in a PPP and what factors (capabilities, expertise, etc.) should FDA consider when establishing or using PPPs? For what areas of science would PPPs be most beneficial to FDA? What types of PPPs does the subcommittee believe FDA should explore?

Charge to the Subcommittee

- The Reagan-Udall Foundation (RUF) is an independent 501(c)(3) not-for-profit organization created by Congress to support FDA's mission by advancing regulatory science and research. RUF leads and collaborates on programs, projects, and other initiatives that further its mission in support of FDA. How can FDA better use the Reagan-Udall Foundation to meet the needs identified in question 1?
- In its 2015 report, [*Mission Possible: How FDA Can Move at the Speed of Science*](#), the Science Board suggested numerous scientific areas in which FDA should invest. How can fellowships address the scientific areas mentioned in the report? Please address this with respect to Senior Fellows, Commissioner's Fellows, Early-Career Fellows, and other types of fellows.

Charge to the Subcommittee

- Another initiative by which RUF can contribute to FDA's mission is through RUF's support of FDA Fellows. In accepting RUF-supported Fellows, FDA will apply its ethics policies and principles to the funding source and the Fellows' activities. Are there any other considerations that FDA should have in accepting Fellows from RUF?

The Scientific Engagement Subcommittee

- Subcommittee established in May 2016.
- Members:
 - Anthony Bahinski, PhD, MBA, FAHA
 - Maria C. Freire, PhD
 - Mark R. McLellan, PhD
 - Bruce M. Psaty, MD, PhD, MPH
 - Dan M. Roden, MD
 - Scott J. Steele, PhD, Chair

The Evaluation Process

- Review of background materials
- Site Visit on June 16, 2016
 - Meetings with FDA senior leadership, OCS, involved Center and Office leadership, Reagan Udall Foundation leadership
- Follow-up on fellowship and PPP programs

Key Findings

Public-Private Partnerships

- PPPs provide a valuable approach to inform and advance persistent and emerging areas of science and technologies that affect regulatory science
- FDA Centers have developed thoughtful approaches to design, implement, and review PPPs

Key Findings

Public-Private Partnerships

Reagan-Udall Foundation for the FDA

- RUF is uniquely positioned to support FDA and convene diverse stakeholders to address needs
- Ability to raise external funds provides RUF significant opportunities and independence to assist FDA (w/ transparency)
- Historical challenges and setting priorities
- Recent developments with RUF

Key Findings

Fellowships

- Fellowship programs used across FDA to promote scientific exchange, support training, and recruitment tool for FDA
- Vital for scientific exchange, future ambassadors and succession planning
- Specific fellowship needs, roles and outcomes sometimes unclear (addressing other needs?)

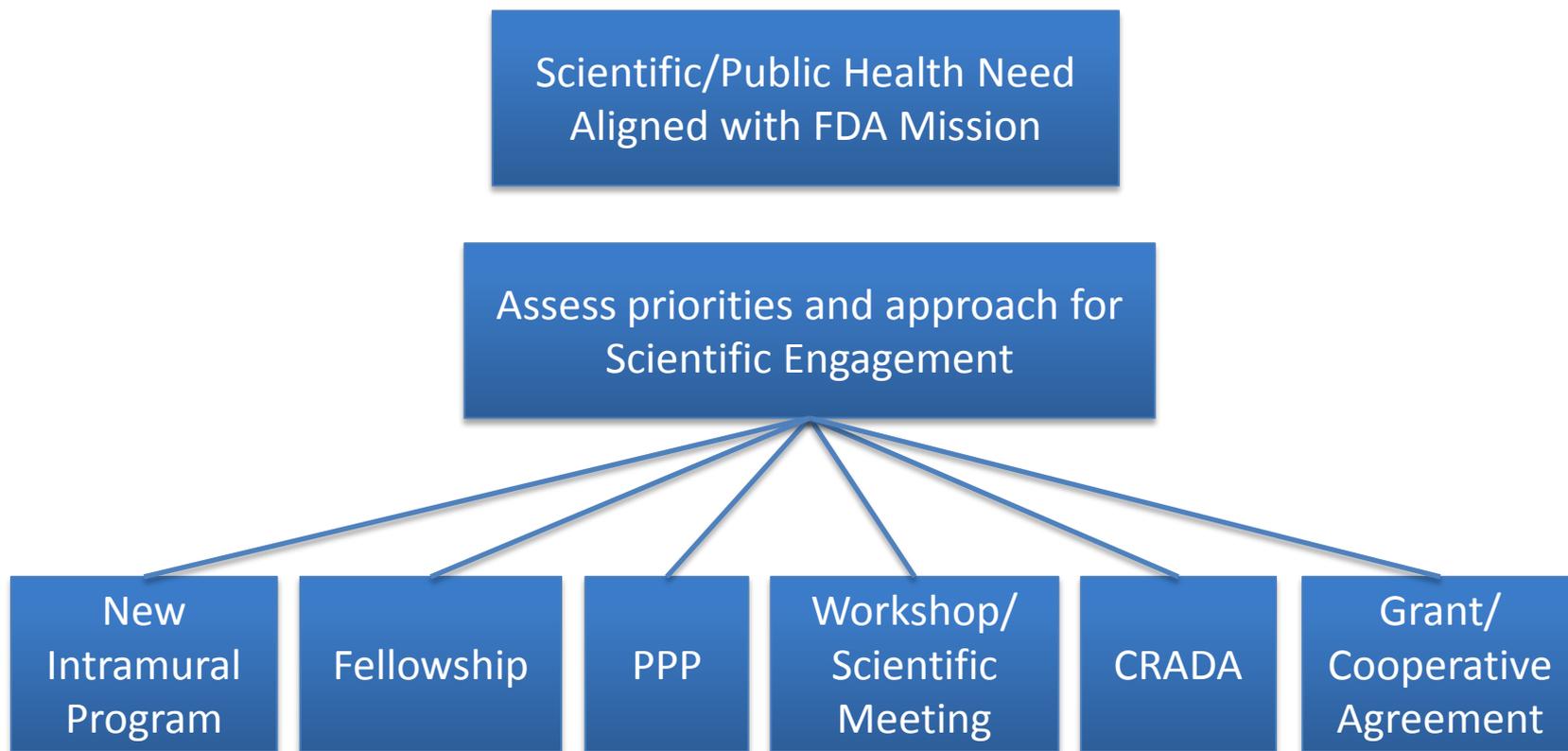
Key Findings

Fellowships

- Real and perceived barriers regarding commercial confidential information and inherently governmental activities
- Interest and challenge with recruiting senior professionals (e.g., Alzheimer's fellowship)
- Continued misalignment of HR processes
- Potential for RUF fellowships

Recommendations

FDA strategic approach to scientific engagement



Recommendations

Public-Private Partnerships

- Likely best for enduring problems and areas of emerging technologies—diverse partners with common goal can pool resources and leverage unique expertise
- Future PPPs should address standards and approaches needed for implementing a range of new and emerging technology areas (e.g., next-gen sequencing, 3D printing, and mobile apps).

Recommendations

Public-Private Partnerships

- **Role for the Office of the Chief Scientist in Supporting PPPs**
 - Create inventory of PPPs, capture and share best practices, advise Centers, provide assessment tools to help Centers evaluate PPPs
 - Senior Science Council could provide input, increase awareness and coordination on current and planned PPPs
 - Support broader portfolio review of PPPs to advise the Commissioner on potential gaps/needs

Recommendations

Public-Private Partnerships

- **FDA Centers' Use of PPPs and Other Mechanisms for Scientific Engagement**
 - Centers generally best positioned to identify priorities and determine the appropriate mechanism to address their scientific engagement needs (and address relevant public health priorities)
 - Centers/offices should have flexibility to develop a broad range of PPPs or other methods of engagement
 - OCS can provide support and maintain a broader inventory and knowledge of the full portfolio of PPPs

Recommendations

Public-Private Partnerships

RUF and PPPs

- RUF should identify support for urgent projects
 - Ensure transparency, address potential conflicts, enhanced access, or undue influence
- RUF should assess unmet needs, with FDA outlining priorities and routinely communicate these to RUF
- FDA (and via other HHS agencies) should explore using additional detailees to temporarily assign federal employees to RUF

Recommendations

Fellowships

- **Clarifying Roles and Needs for Fellows and Other Trainees**
 - Collect data on fellows and more clearly evaluate the current roles and outcomes of the fellowship programs
 - Complete basic needs assessment- determine Center requirements, goals, and capacity to support fellows
 - Short-term: address issues impacting the ORISE program
 - After evaluation of roles and needs- consider changes to ensure programs are primarily being used to address training
 - *Note: any changes must be combined with broader modifications to the hiring and recruitment policies and processes or will create further gaps*

Recommendations

Fellowships

- **Consistent Approach to Commercial Confidential Information and Inherently Governmental Activities**
 - Address inconsistent interpretations and application of Commercial Confidential Information requirements/policies
 - Develop consistent and reasoned approach and interpretation of *inherently governmental activities*
 - Provide ability to access CCI and *participate* in review and *contribute* to developing guidance and recommendations

Recommendations

Fellowships

- **A FDA Intramural Research Training Award**
 - IRTA model used across NIH Institutes and Centers
 - Recognize funding requirements
- **Commissioner's Fellowship Program**
 - Additional track in the Commissioner's Fellowship Program (CFP) – address funding challenges
 - Focus on a rotation in an FDA laboratory, a review group, or other relevant office
 - Coupled with a university-based program (e.g., MS, Certificate, or KL2 program)

Recommendations

Fellowships

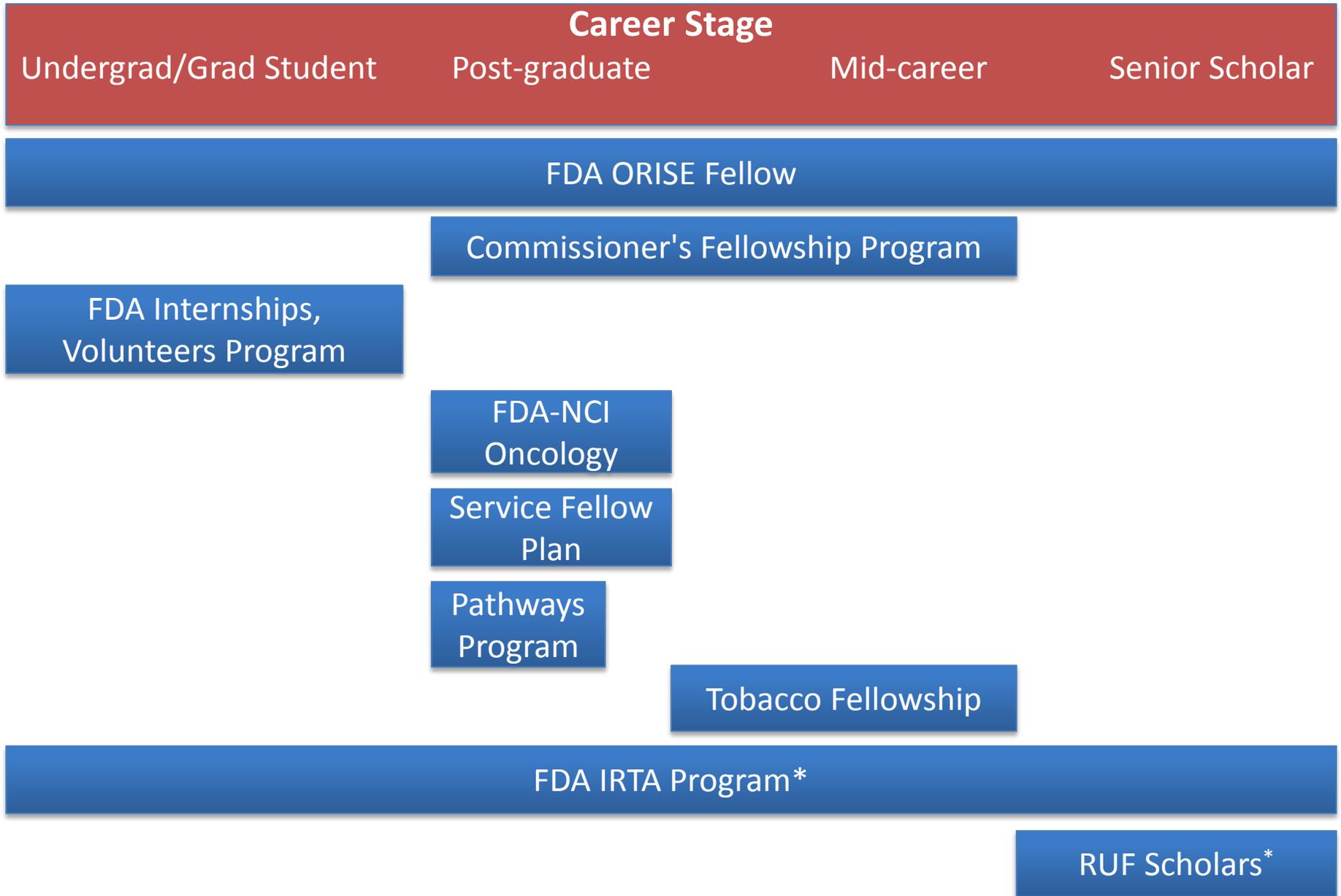
- **Use of Interagency Detailees**
 - Engage federal detailees (bi-directionally) from other agencies
- **Expanding the Research-Reviewer Role for FDA Personnel**
 - Reviewers that maintain active research portfolios and research scientists who support the review process
 - FDA scientists stay engaged in their professional fields and regulatory policy and decision making is informed by recent scientific advancements

Recommendations

Fellowships

- **Critical Role for RUF to Support Fellowships in a Phased Approach**
 - Initial focus on mid or senior level fellows pilot program
 - Assess interest, opportunities and challenges for recruiting fellows
 - Identify stable funding sources (support for even an initial small number of fellows remains a major challenge)
 - After successful pilot, consider expansion and broader cohort
- **Develop RUF Fellowships as Part of a Portfolio of Fellowships**
 - Suite of programs that provide training opportunities across the continuum of career stages and meet FDA's requirements

Alignment of FDA Fellowships



Thank you

- The Scientific Engagement Subcommittee
- FDA leadership and staff