



Scientific Engagement at FDA

**A Report to the FDA Science Board from
the Scientific Engagement Subcommittee**

November 2016

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Executive Summary

Maintaining active interactions with the broad external scientific community is vital for FDA to fulfill its expanding public health mission. It is essential for the Agency to be well positioned to address emerging areas of regulatory science and rapidly advancing technologies.

Scientific engagement also helps FDA accomplish its mission by increasing awareness of FDA's responsibilities and helping with the Agency's critical recruitment and succession planning needs. FDA uses a range of mechanisms for scientific exchange. The Subcommittee was charged with considering:

- a. how FDA can improve its interface with the outside scientific community, particularly regarding public-private partnerships (PPPs) and fellowship programs and
- b. how the Reagan-Udall Foundation for FDA (RUF) can support both of these areas.

Public-Private Partnerships

The Subcommittee found that PPPs provide a valuable approach to inform and advance persistent and emerging areas of science and technologies that affect regulatory science. At the same time, the issues of potential or real conflicts must always be recognized in PPPs, and transparency and external review are essential. The Subcommittee found that:

- FDA should take a strategic approach, including needs assessments, to determine whether the PPP mechanism is well suited to address a specific public health and regulatory science priority under FDA's purview.
- FDA Centers are best positioned to identify specific priority areas and should have the flexibility to determine the appropriate mechanism to address their scientific engagement needs. At the same time, the Office of the Chief Scientist should create an inventory of FDA's PPPs, capturing and sharing best practices, providing assessment tools to evaluate PPPs, and working to identify new opportunities.
- RUF is well situated to further assist FDA with developing needed PPPs. RUF should work with FDA to develop a regulatory science needs assessment and address clear priorities from FDA.

Fellowships

Diverse fellowship programs are used across FDA to promote scientific exchange, to support training, and to serve as recruitment and succession planning tools for FDA. The Subcommittee found that:

- The types and roles of the various FDA fellows should be reviewed and clarified, including tracking the career paths and future productivity of FDA fellows.
- The use of the fellowship mechanism to support technical staff needs at FDA should be discouraged, however any modifications must be linked with increased flexibility and expanded authorities in the hiring process.

- A consistent and functional approach respecting both access to Commercial Confidential Information and policies on inherently governmental activities is critical to enhance fellows' training experience and meet FDA needs.
- The addition of a new flexible FDA Intramural Research Training Award, a separate track in the Commissioner's Fellowship Program, and new RUF fellowships would provide a suite of programs to recruit trainees across the continuum from undergraduate students to senior scholars.
- A phased approach should be initiated to develop RUF fellowship programs, starting with evaluating and implementing a senior scholars fellowship.
- In addition to administrative and logistical challenges, RUF's ability to raise and sustain funding for these programs will be a crucial issue to address. Ultimately, RUF fellowships can provide a vital program to complement a portfolio of FDA fellowships.

Background and Charge

Background

FDA, like other federal agencies, regularly engages the expertise of the external scientific community to advance the Agency's public health mission. Public-private partnerships (PPPs) are one mechanism through which this engagement is often accomplished. PPPs enable FDA to work with industry, academic institutions, public interest groups, and other entities.

PPPs can help advance FDA's public health mission by a) working to fill the knowledge gaps that may delay or impede the development of treatments for diseases and b) harnessing outside expertise to answer challenging scientific questions about, for example, cutting-edge medical products and food safety issues.

Similarly, the intramural research that FDA conducts provides a mechanism for engaging outside scientists at all stages of experience and training by providing temporary employment, instruction, and professional development through fellowship programs. Such fellowships are vital to developing the next generation of regulatory scientists and reviewers.

Charge

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:

- 1) 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?
- 2) 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?
- 3) 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.
- 4) 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?

Process

Subcommittee Formation and Review of Materials

The Subcommittee was established in May 2016 and was composed of the following members:

Anthony Bahinski, PhD, MBA, FAHA
Global Head, Safety Pharmacology
Mechanistic Safety & Disposition, In Vitro/In Vivo Translation
R&D Platform Technology & Science
GlaxoSmithKline

Maria C Freire, PhD
President and Executive Director
Foundation for the NIH

Mark R. McLellan, PhD
Vice President for Research
Dean of the School of Graduate Studies
Utah State University

Bruce M. Psaty, MD, PhD, MPH
Co-director, Cardiovascular Health Research Unit
Professor, Medicine & Epidemiology
University of Washington

Dan M. Roden, MD
Professor of Medicine, Pharmacology, and Biomedical Informatics
Vanderbilt University School of Medicine
Senior Vice-President for Personalized Medicine
Vanderbilt University Medical Center

Scott J. Steele, PhD
Subcommittee Chair
Director, Regulatory Science Programs
Deputy Director, Goergen Institute for Data Science
Associate Professor, Public Health Sciences
University of Rochester

Site Visit

A site visit was held on June 16, 2016, at FDA (White Oak). The agenda is included in Appendix A. The visit included critical overviews and discussions from key leaders from across FDA and the Reagan-Udall Foundation for FDA.

Key Findings

A strong scientific foundation and the exchange of scientific knowledge are critical for FDA to carry out its mission to protect and promote the public health. Indeed, the FDA Science Board has been particularly focused on approaches that would enable FDA to ensure that it is able to conduct its scientific and regulatory mission. To that end, the Science Board has released a number of reports providing recommendations on these topics (*FDA Science Mission at Risk*, 2007; *Mission Possible: How FDA Can Move at the Speed of Science*, 2015).

FDA has launched several plans and initiatives to advance regulatory science and to enhance external scientific engagement (*Advancing Regulatory Science for Public Health*, 2010; *Advancing Regulatory Science at FDA*, 2011). These plans have resulted in informal and formal activities and partnerships led by FDA groups, Offices, Divisions, and Centers.

The Office of the Chief Scientist has specifically led scientific engagement initiatives designed to cut across FDA Offices and Divisions (e.g., the FDA Science Forum, Commissioner's Fellowship Program, Centers of Excellence in Regulatory Science and Innovation program, and the Regulatory Science Broad Agency Announcements). These activities can take the form of conferences and workshops, Cooperative Research and Development Agreements (CRADAs), external grants, scientific exchanges, establishing new intramural programs, and the formation of PPPs.

Some Centers have identified clear roles for PPPs that are relevant to the products they regulate to address their scientific needs. Other Centers/Offices use different mechanisms, such as workshops and scientific conferences to engage the scientific community and exchange information.

Public-Private Partnerships

Value and Strategic Approach to Developing PPPs

PPPs have the potential to provide a powerful mechanism to collaboratively leverage resources and expertise across a broad range of stakeholders with a common interest, an approach that is likely to benefit all partners and enhance public health. These PPPs are particularly well suited to address and inform enduring and emerging science and technologies that may affect regulatory science, promoting information-sharing among relevant parties.

It is critical for FDA to be prepared for emerging technologies and to exchange knowledge with leaders in these fields and technology areas. The Subcommittee found FDA's approach to using PPPs at several levels to be quite diverse and robust (Table 1). The Centers have developed thoughtful approaches to design, implement, and review PPPs. This process and existing models should be shared across FDA.

Table 1. Examples of active FDA public-private partnerships

Organization	Program/Project
Critical Path Institute (CPI)	Coalition Against Major Diseases Consortium (CAMD) Predictive Safety Testing Consortium (PSTC) International Neonatal Consortium (INC)
Foundation for the NIH (FNIH)	Biomarker Consortium (BC)
Clinical Trials Transformation Initiative (CTTI)	Large Simple Trials Central IRBs
Medical Device Innovation Consortium (MDIC)	Patient-Centered Benefit-Risk Assessment Computer Modeling & Simulation
America Makes	Advanced Manufacturing of Biomedical Devices from Bioresorbable Metallic Alloys for Medical Applications
Reagan-Udall Foundation for the FDA (RUF)	Innovation in Medical Evidence Development and Surveillance (IMEDS)

Safe Harbor Requiring Transparency and Review

PPPs established through a 501(c)(3) mechanism can provide a safe harbor to share information and address research areas in the pre-competitive space. However, even in an apparent safe harbor situation, such as the 501(c)(3), the issues of potential or real conflicts must always be recognized and managed.

In the setting of a PPP, FDA staff will interact with individuals, for example, from academia, patient advocacy groups, and industry, who may have a real or perceived agenda in terms of seeing particular policies, actions, technologies, or methods moved forward and others not promoted. For example, individuals from academia may have methods they have developed that they are interested in seeing widely adopted. Likewise, industry members may have an interest in seeing approaches developed that reduce regulatory requirements for drug approval.

In the setting of moving forward selected aims, the influence may be subtle and appear in the form of unexamined assumptions. Further, the level of personal interactions at these venues can carry with it a risk of perceived enhanced access. These situations should be identified up front to ensure transparency. An independent review by non-affiliated individuals should be considered as routine to address any perceived and real conflict as these PPPs issue recommendations.

Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA (RUF) is an independent 501(c)(3) entity created by Congress via the Food and Drug Administration Amendments Act of 2007 (FDAAA 2007) to advance the regulatory science and public health missions of FDA. Similar to the Foundation for the National Institutes of Health (NIH) and other congressionally mandated foundations that support particular federal agencies, RUF is uniquely positioned to support the mission of FDA and to work with FDA to convene diverse stakeholders from government, industry, academia, and patient groups to address regulatory science needs.

RUF activities can take multiple forms: creating PPPs, developing and providing awards for specific projects, convening workshops and meetings, and establishing training programs, among others. Although the statute provides for a modest level of FDA direct support to RUF, the foundation can and must solicit external funds to support its initiatives.

The ability to raise external funds provides RUF with significant opportunities, independence, and flexibility to assist FDA in its mission, particularly given the challenges with the current federal budget and FDA's limited resources to support new programs. Although FDA should lead the identification of scientific, regulatory, and human resources needs and determine which projects/programs it presents to RUF for consideration, FDA cannot discuss funding needs with potential donors.

Bilateral conversations between companies and agencies on programs in which they are potential funders create problems of perception and undue influence. The need for transparency and independence is critical. The law includes several provisions to ensure independence and public accountability.

RUF, therefore, plays a unique role to help facilitate these PPPs and catalyze scientific collaborations and exchanges. RUF also has the ability to embark on projects and programs that FDA does not bring to the table but that support FDA's mission. Any project this mechanism develops would also require transparency and independent review, and should still be developed in close coordination with FDA to ensure it aligns with their needs and mission and to avoid redundancy with existing programs.

Challenges

Despite the provisions to ensure transparency and independence, there were Congressional concerns and delays in the initial establishment and funding of RUF, contributing to significant barriers to launching projects and challenges to ensure stable RUF leadership and staffing.

The law outlines a process for FDA to communicate priorities to RUF and for RUF to develop a regulatory science needs assessment. Clearly this process needs to be undertaken in a more proactive and robust manner. Challenges in funding and staffing for RUF remain a significant barrier in selecting and launching projects, preventing it from realizing its full potential. Recent steps have been taken to enhance some of RUF's operations, including: 1) the recent selection of a new Executive Director; 2) expansion of the RUF Board; and 3) renewed efforts to raise funds to support RUF initiatives.

Fellowships

A range of fellowship programs is used across FDA to promote scientific exchange, support training, and as recruitment tools for FDA (Table 2). Trainees also serve as future ambassadors, who will go into academia, industry, government or other sectors with knowledge of FDA and potentially become future partners in product development and in addressing public health issues.

The recruitment of fellows and other trainees also plays a critical role in FDA's succession planning, increasing the availability and interest of professionals knowledgeable and capable of assuming a range of roles at FDA. One prominent program is the Commissioner's Fellowship Program, which includes

both substantial course work and hands-on regulatory science experiences at FDA. Another potential but not fully realized role for fellowships is the opportunity for senior leaders in academic medicine to receive support for spending time at FDA, furthering their own understanding of issues in regulatory science, and bringing their experience and expertise to FDA.

Table 2. List of primary FDA fellowship programs for post-graduate trainees and scholars

Mechanism	Program Example	Eligibility	Program Goals, Requirements, and Outcomes
Title 42 209(g) <i>Access to CCI and may perform inherently governmental activities</i>	Commissioner's Fellowship Program	Post-graduates with doctorate except for engineers within 7 years of degree	Goals <ol style="list-style-type: none"> 1. Attract top-tier scientists to FDA to address regulatory science issues through mentored projects of high priority to the Agency 2. Provide regulatory science training 3. Serve as a potential recruiting tool. Requirements <ol style="list-style-type: none"> 1. Mentored project 2. Courses 3. Regulatory experiences.
Title 42 209(g) <i>Access to CCI and may perform inherently governmental activities</i>	Service Fellowship Plan	Within 7 years of degree	Provides flexible mechanism for the temporary employment, training and professional development of promising research/regulatory scientists.
InterAgency Agreement with Department of Energy <i>Access to CCI</i>	FDA ORISE Research Program	Student; Post-graduate within 5 years of degree; Faculty	Goals <ol style="list-style-type: none"> 1. Continue their research/education 2. Enhance professional development in specific areas 3. Become familiar with research areas 4. Become interested in future careers in fields related to FDA

Mechanism	Program Example	Eligibility	Program Goals, Requirements, and Outcomes
Interagency Agreement with NCI/NIH <i>Access to CCI</i>	FDA – NCI InterAgency Oncology Task Force Fellowship Program	Doctorate within 5 years of degree	Overarching objectives for program <ol style="list-style-type: none"> 1. To train a cadre of scientists in research and research-related regulatory review, policies, and regulations to develop a skill set bridging two disparate processes. 2. To build awareness of regulatory requirements into the early stages of product development processes. 3. To improve planning throughout research and regulatory review to facilitate the movement of novel approaches from the bench to the community. 4. To facilitate the movement of drugs, biologics, and devices from basic bench science to commercialization.
Title 5 <i>Access to CCI and may perform inherently governmental activities</i>	Pathways Program for Recent Graduates	Within 2 years of degree	Provides employment opportunities through meaningful training and career development opportunities for individuals who are at the beginning of their Federal service
Contract with National Academies <i>Access to CCI</i>	Tobacco Regulatory Science Fellowship	Mid-career professionals	Gain experience and expertise to further define and develop the field of regulatory science as it relates to the regulation of tobacco products

CCI: commercial confidential information

One significant source of fellows for FDA that is also used by other Federal departments and agencies is the Oak Ridge Institute for Science and Education (ORISE) program. The Department of Energy (DoE), via a contract to the nonprofit Oak Ridge Associated Universities, supports the ORISE program to develop science, technology, engineering, and mathematics (STEM) training experiences for students, postgraduates and faculty.

The FDA ORISE Research Program was established via an interagency agreement with DoE. It is the largest program (~80% of the nearly 1,400 fellows at FDA) used across FDA's Centers and Offices to bring students, post-graduates, and faculty to FDA to support scientific exchange and professional development. Importantly, this program permits participation of foreign nationals, sponsoring visas for fellows.

Although all of the programs outlined in Table 2 officially allow fellows and trainees access to commercial confidential information (CCI) generally required for regulatory review activities, only Title 42 and Title 5 fellows who are FDA employees may perform *inherently governmental activities*. *Inherently governmental activities* are interpreted to include representing FDA and obtaining training

experiences, such as serving as a review author and/or presenting at an Advisory Committee meeting. In practice, the Subcommittee found that there are varying interpretations as to which fellows can access CCI and potentially participate in the different aspects of regulatory review. Specifically, the lack of a clear and consistent approach to defining *inherently governmental activities* hampers these training programs.

A recent review of the entire ORISE program (GAO-16-128: Published: Jan 20, 2016), issues of defining *inherently governmental activities*, and efforts to ensure consistency in the program's use is creating significant challenges for FDA in planning and addressing fellowship and internship needs.

One challenge with the FDA ORISE program is the lack of detailed outcome measures and an assessment of how the program is being used across FDA. Discussions during the site visit raised the possibility that the FDA ORISE Program was also being used to address pressing, broader research and technical staff needs. Putting in place measures to assess program outcomes would be a way to determine whether and to what extent these issues may exist.

Attracting mid- or senior-level scientists and other professionals for a fellowship or rotation is an FDA priority and challenge, although the specific need and level of interest for these scientists was difficult to gauge. The previously proposed Alzheimer's fellowship initiated by RUF is an informative example that encountered challenges and provides lessons learned to create an effective model for developing, funding, and launching these programs, including:

- a) accurate assessment of the level of interest from potential candidates
- b) perceived conflicts of interest based on the program sponsor (even if a foundation)
- c) the need for a key advocate and mentor at FDA
- d) the ability to identify a relevant mid- to senior-level professional who is able to accommodate the funding structure
- e) timing and other logistical constraints of a sabbatical at this stage in their career
- f) difficulty with the contract mechanism, and
- g) issues with sustaining a training program, such as this, once it is launched

As highlighted in previous reports, the human resources process does not currently function in such a way as to provide increased flexibility in salaries, hiring authorities, and merit increases. Conflict of interest restrictions and other processes at FDA also have an impact on the ability to recruit and retain trainees and fellows (*Mission Possible: How FDA Can Move at the Speed of Science*, 2015). These human resource hurdles appear at times to contribute to the use of fellowship awards to support the hiring of technical staff, rather than to create genuine training opportunities.

Potential for RUF Fellows

To date, RUF has not used its statutory authority to establish fellowship programs so as to place a range of professionals who are not employees of regulated companies at RUF, academic or scientific institutions, or FDA (FDAAA 2007). The statutory authority is designed to foster regulatory science training and scientific exchange, and the law grants RUF fellows the ability to access commercial

confidential information (CCI). However, they cannot perform *inherently governmental activities* during this period. The ability of RUF to use diverse funding sources to support training programs makes RUF fellowships particularly attractive.

Recommendations

FDA Strategic Approach to Scientific Engagement

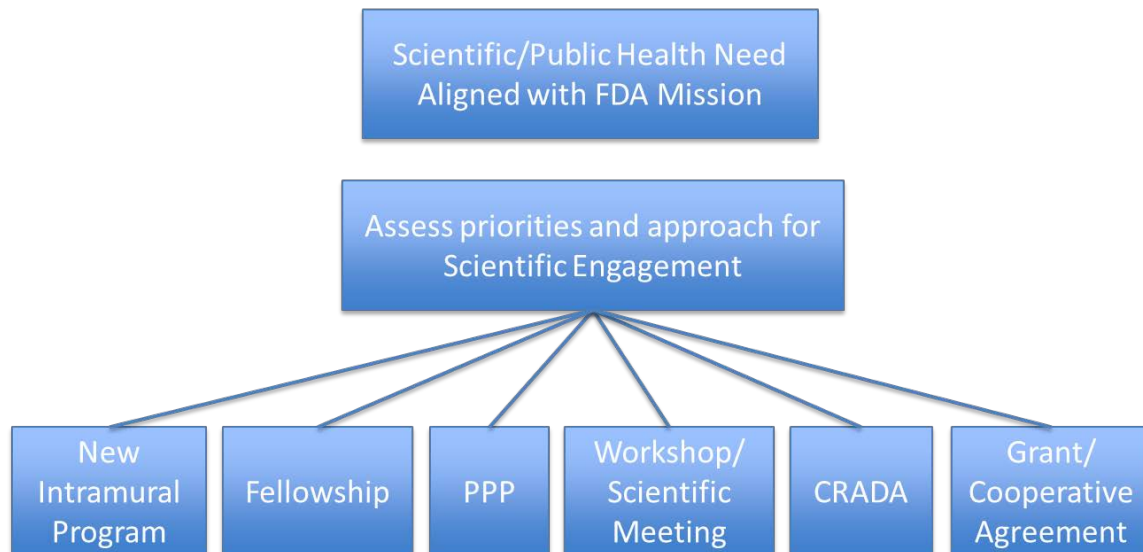


Figure 1. Strategic view and approach to FDA’s diverse mechanisms for scientific engagement

To fulfill its requirements, FDA effectively uses a range of mechanisms for engaging with the scientific community. Centers should continue to have the flexibility to choose the optimal methods to meet their requirements. FDA should continue to define public health and regulatory science priorities under its purview, assess its needs based on these areas and existing FDA programs/expertise (intramural and extramural), and then determine its requirements/gaps. Meeting these requirements can be achieved through various mechanisms, such as: grants, contracts, cooperative research and development agreements (CRADAs), Material Transfer Agreements (MTAs), workshops/meetings, PPPs, and, in some cases, developing new intramural programs (Figure 1).

Public-Private Partnerships

PPPs should be considered as one of many potential mechanisms for FDA to carry out its mission to protect and advance public health (Figure 1). PPPs likely work best for enduring problems and areas of emerging technologies, whereby diverse partners with a common goal are needed to jointly pool their resources and leverage unique expertise.

FDA has already established several valuable PPPs; future PPPs should address standards and approaches needed for implementing a range of new and emerging technology areas (e.g., next

generation sequencing, 3D printing, and mobile apps). The resulting guidance documents, methods papers, and relevant data and findings generated from demonstration projects will advance key areas of regulatory science. Throughout this process, attention needs to be paid to the potential issues of perceived and real conflicts of interest and enhanced access discussed above.

Role for the Office of the Chief Scientist in Supporting PPPs

The Office of the Chief Scientist (OCS) should play a key role in creating an inventory of FDA's PPPs, to accumulate relevant experiences, capture and share best practices, and provide assessment tools that can help the Centers/Offices to evaluate the return on investment and risk/benefit for their participation in PPPs. Using these best practices and assessment tools, OCS would advise Centers as they consider new PPPs or evaluate existing partnerships.

The Senior Science Council could provide an effective venue to provide this input, as well as increasing awareness and coordination with other Centers and Offices that might be considering (or already have existing) PPPs with similar goals. OCS can also support a broader portfolio review of PPPs to advise the Commissioner on potential gaps/needs.

FDA Centers' Use of PPPs and Other Mechanisms for Scientific Engagement

The Subcommittee recommends that the Centers are best positioned to identify priorities and determine the appropriate mechanism to address their scientific engagement needs, whether via PPPs, workshops, scientific conferences, or other mechanisms. Centers/offices should have the flexibility to develop a broad range of PPPs or other methods of engagement that address relevant public health priorities and their specific needs. When using PPPs, FDA should ensure that those PPPs are addressing clear needs and are being evaluated. OCS can provide support (as noted above) and maintain a broader inventory and knowledge of the full portfolio of PPPs.

RUF and PPPs

Unique Role

RUF is well situated with unique authorities and the mission to address FDA's PPP needs, while FDA will continue to use a range of other effective PPPs that the Centers have identified. RUF has significant potential and should be supported and leveraged. Sustained funding will be critical for RUF to achieve its goals. A top priority for RUF should be engaging donors and funders to provide support for urgent projects. RUF will need to explore a range of funding initiatives, and in considering the source of external funds and how they will be directed, it is vital to ensure transparency and address potential conflicts, enhanced access, or undue influence for funders and donors.

Setting Clear Priorities from FDA

FDA should ensure it is providing a needs assessment, setting clear priorities, and routinely providing this information to RUF. FDAAA 2007 stipulates that RUF will conduct and update an assessment to "identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including post-approval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics, and including the incorporation of more sensitive and

predictive tools and devices to measure safety”¹ and that it will use this assessment to establish goals and programs (while reviewing existing and planned HHS programs) in close coordination with HHS/FDA. This process should be implemented to set clear goals and recommended programs.

Detailees to RUF

FDA (and via other HHS agencies) should explore using additional detailees to temporarily assign federal employees to RUF for relevant scientific projects, training programs, and general administrative and project management assistance to help support RUF, particularly as it expands these efforts over the next few years. The authorities to provide detailees are outlined in FDAAA 2007.

Fellowships

Clarifying Roles and Needs for Fellows and Other Trainees

FDA should establish a mechanism to collect data on fellows and more clearly evaluate the current roles and outcomes of the fellowship programs. A needs assessment should also be completed across FDA Centers to determine their requirements, goals, and capacity to support fellows.

The Commissioner’s Fellowship Program appears to be one of the few fellowship programs that have data available to address these questions. The FDA ORISE Research Program is addressing a broad range of FDA needs due to critical funding constraints and human resource hurdles. Although some trainees are used for postdoctoral fellows and faculty rotations, the Subcommittee was informed that others appear to serve as technical staff and research scientists.

As a short-term recommendation, FDA should address administrative, policy, and planning requirements related to the ORISE program, working within HHS and the DoE, as necessary. As a next step, the diverse roles being addressed by the FDA ORISE Research Program should be more carefully analyzed and separated as necessary, to ensure that these programs are primarily being used to address training needs, in combination with the broader needs assessment outlined above.

If the current fellowship programs are also used to address key technical staff needs and other roles, any changes must be combined with broader modifications to the hiring and recruitment policies and processes. These broader changes to hiring practices have been identified previously and present significant challenges, but must be coupled with any modifications to the fellowship programs. Independent changes to the fellowship programs will create further gaps in technical staff needs. Additionally, as FDA recruits fellows and other trainees, FDA should also consider mid- to long-term succession planning to help address critical needs across the Agency.

Consistent Approach to Commercial Confidential Information and Inherently Governmental Activities

To enhance fellows’ training experience and meet FDA needs, fellows should generally have the ability

¹ FDAAA 2007, Available at:

<http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm>, accessed Oct. 25, 2016.

to access CCI and participate in aspects of regulatory review, at the discretion of the Agency, based on the fellows' role and responsibilities.

As a parallel example, in other government agencies, security clearances can be granted to fellows who are not federal employees in roles that require their access and contribution to the analysis of classified national security information, without fellows officially representing or making decisions on behalf of an agency.

Given the significantly more complex nature of handling and analyzing classified information, FDA should explore and implement a process, including legislative initiatives, if necessary, whereby fellows who are not FDA employees can access and analyze CCI. In this way they could contribute to regulatory review with the appropriate safeguards to ensure that they were not officially representing FDA. Conflicts of interest, real or perceived would also be addressed. FDA should also use a consistent and reasoned approach and interpretation of *inherently governmental activities*. These issues should be managed across FDA in a transparent and standard approach that addresses appropriate concerns, while ensuring a productive and beneficial training experience.

A FDA Intramural Research Training Award

To address the broader challenges concerning FDA's ability to recruit trainees at the undergraduate, graduate, post-doctoral, and other levels, FDA should seek any required authorization to establish a robust and flexible Intramural Research Training Award (IRTA), similar to the IRTA program actively used by the National Institutes of Health's (NIH) Institutes and Centers.

NIH has a centralized and successful IRTA program as part of a broad range of training initiatives coordinated by the NIH Office of Intramural Training and Education. Although this scale of activity may not be required, the IRTA and related intramural training programs would be a critical asset to support FDA. As noted previously, it would be essential to ensure that any amended or new legislation, as necessary, permits trainees to have access to CCI and participate in aspects of regulatory review. Adequate funding plans to support the program must also be considered.

The Commissioner's Fellowship Program

To provide additional flexibility for fellowship opportunities and to address FDA needs, an additional track in the Commissioner's Fellowship Program (CFP) should be established. The current CFP would continue with its additional focus on course work, while a second track would be established with a primary research or review focus. This track would focus on a rotation in an FDA laboratory, a review group, or other relevant office. The fellowship could be coupled with a university-based program (e.g., MS, Certificate, or KL2 program) and a previous report to the Science Board on the CFP recommended that FDA work with academic partners to establish the CFP as an experiential component of a formal degree program. (*FDA Commissioner's Fellowship Program*, 2015). While these would be targeted rotations as part of an academic program, there would be funding considerations to support the fellow during the actual period of the rotation at FDA. Additionally, the overall CFP program requires increased and sustained funding support.

Use of Interagency Detailees

To promote scientific exchange with other science and research agencies, FDA should engage federal detailees (bi-directionally) from other agencies (e.g., NIH, Center for Medicare and Medicaid Services, Centers for Disease Control and Prevention, and Department of Defense) that have active research programs and can provide additional opportunities for scientific engagement and professional development.

The Researcher-Reviewer Role for FDA Personnel

Centers have employed diverse approaches to maintain scientific awareness for their scientists, clinicians, engineers, and other professionals. For example, there are many reviewers who maintain active research portfolios and there are many research scientists who support or provide consultations for the review process. Research ranging from discovery science to clinical research applied to solving FDA's regulatory science questions helps reviewers acquire the most up-to-date knowledge that bolsters their study design, analytic and review skills, while also informing regulatory policy and decision making. Centers should consider increasing these types of roles, including for junior scientists, as a way to ensure FDA scientists stay engaged in their professional fields as well as maintain professional relationships with the external scientific community.

Critical Role for RUF to Support Fellowships in a Phased Approach

RUF should play a vital role in supporting fellowships at FDA by using its unique authorities. Based on FDA's strong desire to specifically attract later-career fellows, the Subcommittee believes an initial area for RUF to concentrate its efforts on would be piloting fellowships for senior scientists.

RUF should begin assessing the interest of relevant mid- to senior-level subject matter experts (SMEs) in spending time as senior fellows/scholars at FDA. This survey could begin with current Special Government Employees (SGEs) serving on FDA advisory and other committees. RUF would gather comments and feedback on issues of interest in a fellowship opportunity, ideal timing and duration, the topics and areas of interest, and funding needs, among other questions. This could include a public workshop to gain broader feedback and engagement, based on the results of the survey.

In addition to academia, perhaps senior fellows could also come from patient advocacy groups, and industries that are not regulated by FDA. Other technology sectors could potentially participate to provide different perspectives. The information from the survey and workshop, tied to a clear outline of FDA Centers' goals and needs, would be helpful for RUF to both proactively and opportunistically identify external support to fund a successful new RUF senior fellowship or scholars program at FDA.

This initial senior scholars fellowship would serve as a pilot to meet an FDA need, while also determining how to address a number of challenges to expanding programs, including issues of identifying FDA mentors and prospective trainees, timing and logistics of placing fellows, and RUF's ability to raise and sustain funding for these programs. Identifying stable funding sources for even an initial small number of fellows remains a major challenge.

After the senior fellow program is successfully launched, RUF could begin applying this model and lessons learned to support other broader fellowship opportunities at FDA. This might include evaluating future support for the CFP. More broadly, RUF and FDA can help create a cohort of fellows and explore team-based fellowships that reinforce core competencies, along with research experiences at FDA.

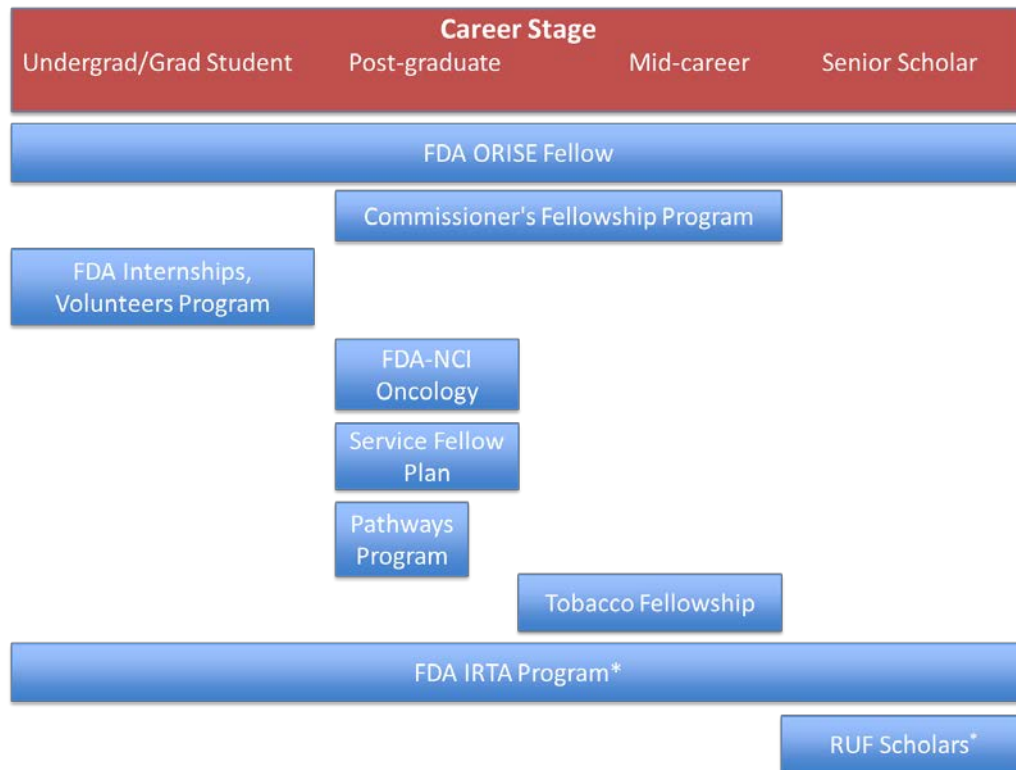


Figure 2. Comparison and alignment of current and proposed FDA fellowships (*Indicates newly proposed programs). Selected fellowship programs are represented by bars mapped against the corresponding career stage/eligibility for the indicated program.

Develop RUF Fellowships as Part of a Portfolio of Fellowships

FDA should actively engage RUF in developing the RUF fellowships to ensure they complement existing programs, providing a menu of fellowships with different participants and designed to address diverse goals. Ultimately, maintaining a broader suite of programs that provide training opportunities across the continuum of career stages will allow for a flexible approach to meet FDA's requirements (Figure 2). This approach will ensure FDA maintains a level of control to address its needs, while providing expanded opportunities and additional funding mechanisms to support training and scientific engagement.

Appendix A

Scientific Engagements Subcommittee Site Visit

Agenda

Thursday, June 16, 2016

FDA White Oak Campus

Building 32, Room 5344

Start	End	Topic	Speaker/Participants
8:30 am	8:45 am	Challenges and Charge	Lu Borio
8:45 am	9:30 am	PPPs: FDA's Experience with Establishing PPPs	Matt Warren
9:30 am	10:00 am	FDA Fellowships	Leslie Wheelock
10:00 am	10:45 am	FDA and RUF: History	Lisa Rovin
10:45 am	11:00 am	Break	
11:00 am	12:00 pm	Commissioner's Perspective	Robert Califf
12:00 pm	1:00 pm	Working Lunch	
1:00 pm	2:00 pm	RUF Executive Director	June Wasser
2:00 pm	3:00 pm	FDA Centers' Views	Center Reps
3:00pm	4:00 pm	Subcommittee Discussion	
4:00pm		Adjourn	