Centers of Excellence in Regulatory Science and Innovation (CERSI) --- Program Evaluation

A Report to the FDA Science Board from the CERSI program Evaluation Subcommittee

February 25, 2016

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Executive Summary

As a part of its mission to advance regulatory science, the Office of the Chief Scientist at FDA established the Centers of Excellence in Regulatory Science and Innovation (CERSI) program in 2011. In 2015, following the second round of grants that established a total of four CERSIs, a Subcommittee of FDA's Science Board was tasked with evaluating the CERSI program to date and making recommendations for the program going forward.

Details of the charge from the Science Board are within this report. At a high level, the Subcommittee was to review how effectively the CERSI program addressed FDA's agenda as it related to regulatory science research, education/training, and the program's administration.

The Subcommittee conducted a thorough evaluation, the cornerstone of which was an extensive site visit. The site visit encompassed candid discussions with leadership from each of the four existing CERSIs, and, separately, with key FDA leadership, including from the centers, as well as FDA staff involved in administrating the CERSI program.

Highlights of Key Findings

As an overarching finding, the Subcommittee strongly believes that FDA must continue to be a key contributor to advancing regulatory science. FDA is uniquely positioned to understand the current limitations of its science base and to identify best what research and education programs are most critical to its mission.

The Subcommittee found that FDA has very limited funding to apply to regulatory science research and training and that it is not traditionally a funding agency. However, the lack of appropriated FDA budget dedicated to substantially funding a portfolio of regulatory science research limits its effectiveness in prosecuting its critical research and training agenda, including the CERSI program.

Specific to the CERSI program, the Subcommittee believes that each of the CERSIs has contributed to FDA's advancement of regulatory science, with the newer sites leveraging existing long-standing relationships in support of FDA's scientific development.

These contributions, however, do not appear to be aligned with each other. Although each of the CERSI's contributions fall within the scope of FDA's stated regulatory science priorities, these priorities are very broad and general. Therefore, it is not clear if the CERSIs, individually or collectively, are addressing the most pressing issues for FDA or

the public FDA serves. Further, discussions with key personnel within FDA's centers raised issues for the Subcommittee as to the centers' role in choosing CERSIs, their specific projects, and how these projects are managed.

Internal stakeholders also provided disparate views on how the educational offerings of the CERSIs might best address FDA's educational needs, as well as those of its external stakeholders (e.g., translational researchers in academia or industry scientists).

Also beyond the scope of this report, but affecting the CERSI's effectiveness are FDA's human resource challenges—chronic vacancies among them. Combined with limited professional development funding, these challenges redound to insufficient time and financial support for FDA scientists to optimally contribute to advancing FDA's regulatory science initiatives and engagement.

Highlights of Key Recommendations

- **More explicit definition of the CERSI program's scope, with clear goals that allow for metrics of achievement**. Underlying this recommendation is the need for a more explicit strategic roadmap of FDA-wide regulatory science research and education priorities. Any such roadmap must be developed and maintained through collaborative and iterative input from the Office of the Chief Scientist and each of the relevant FDA centers to identify their priorities. This will provide FDA and future external evaluators clearer metrics by which to judge the success of the CERSI program overall, as well as each individual CERSI institution. Not having this, the Subcommittee encountered several challenges to evaluating the impact of the CERSI program in helping FDA to achieve its aims in regulatory science education and research. Therefore the report's recommendations presume the CERSI program is of sufficient merit to continue and leaves it to FDA to determine the CERSI program's relative importance in meeting FDA's overall objectives.

- **Provide for responsive governance and portfolio management.** A transparent governance structure and process is required to ensure the CERSI program's effective project and portfolio management and how it fits into the ORSI/FDA broader regulatory science agenda and needs. Project managers should be identified at FDA and the CERSIs, with ORSI serving as a facilitator and joint project manager, and ensuring there is a center-level liaison/project manager at each relevant FDA center or office. ORSI should serve as a facilitator between FDA centers and CERSIs to help identify and coordinate lists of potential projects.

- **Create an effective CERSI network and collaborations among the CERSIs, FDA, industry, and academia**. FDA's regulatory science research and educational efforts would be greatly enhanced by a coordinated effort to ensure optimal leveraging of expertise and efforts, while minimizing unnecessary redundancies. This is predicated on the strategic roadmap, accompanied by effective internal and external communication. Ideally, more durable funding would be provided to the existing CERSIs with further CERSIs added as the network and needs dictate. The Subcommittee also strongly encourages FDA to seek means to expand its regulatory science efforts to better align with and leverage translational science and broader innovation principles as well as education efforts since these are overlapping areas of interest and science.

- **Coordination and sharing of educational resources**. Leveraging work, such as the recently developed regulatory science educational competencies, the Subcommittee recommends that FDA oversee development of an educational resource, working to align and make transparent the efforts and outputs from the CERSI institutions, as well as other academic organizations and foundations. Additionally, expanding fellows' ability to engage meaningfully in FDA activities (policy, science, and review) is highly recommended, including flexible approaches to addressing restrictions on access to proprietary data.

I. Background and Charge

Background

As FDA's mission expands and becomes increasingly complex, FDA strives to ensure that its review and regulatory decisions are evidence-based and informed by the latest science. In launching the Centers of Excellence in Regulatory Science and Innovation (CERSI) program, FDA sought, through extramural partnerships, to address gaps in relevant science not specifically addressed by other agencies. It also aimed to focus broader interagency attention on key gaps in knowledge, tool development, and infrastructure necessary to support innovative medical product development. The CERSIs were formed with the belief that regulatory science and translational research should tackle these gaps through a collaborative and cross-disciplinary approach.

In 2011, as part of FDA's commitment to build cross-agency capacity around regulatory science, FDA's Office of Chief Scientist (OCS) established the CERSIs, focusing on two areas:

1. Targeted research projects
2. Cross-disciplinary regulatory science training

To ensure close cooperation in the early stages, two local universities were selected to receive three-year funding through a cooperative agreement (U01) mechanism. These awards were made to Georgetown University (GU-CERSI) and the University of Maryland (M-CERSI). In 2013, a second competitive application process without geographic limitations was announced to establish additional CERSIs. The second round included awards to a joint proposal between the University of California at San Francisco (UCSF) and Stanford University as well as to Johns Hopkins University (JHU).

FDA originally envisioned that three years of Agency funding would enable the CERSIs to become established and institutionalized within their academic centers while intra- (within the university) and extramural sources of support through public–private partnerships would be developed to enable each CERSI to be self-sustaining. However, since that has not occurred with the first two CERSIs, FDA has elected to continue to provide them with financial support, albeit at lower levels than during the initial funding period.

Charge

With the initial funding period for the first two CERSIs completed and the second round of new CERSIs established, the Office of Regulatory Science and Innovation (ORSI) in OCS asked the Science Board to convene a subcommittee to evaluate the CERSI program. FDA suggested that the following questions be answered. The questions are categorized according to the following focus areas of CERSI operations: Overall Missions, Scientific Research Projects, Education and Training Projects, and Administration and Infrastructure.

1. Overall CERSI Missions

- Do the established roles and functions for CERSIs and for the CERSI network appropriately advance FDA's regulatory science needs and priorities? Could the roles and functions be modified or enhanced to further advance FDA's regulatory science needs and priorities?
- What criteria should be used to measure the overall success and impact of CERSIs and the CERSI network for FDA and the participating academic centers?

2. CERSI Scientific Research Projects

The Program Scope, Goal, Objectives, Achievements, and Impacts (Expectations)

- What model(s) can be used to identify and develop scientific research projects that are conducted by each CERSI?
- Should the CERSI network engage in multi-CERSI or cross-cutting scientific research projects? If so, what types of research projects would be most appropriate?
- What metrics should be used to evaluate the impact of individual CERSI scientific research projects and the overall scientific portfolio for FDA, for the academic centers, and for other stakeholders? (Some potential options are listed below.)
    - Improvement of FDA performance through CERSI research project outcomes (e.g., national and international standards, guidance and policy documents, and congressional reports).
    - Improvement of FDA engagement with the scientific community and other stakeholders, especially in new sciences and emerging technologies.

3. CERSI Education and Training Projects

The Program Scope of Work, Goal, Objectives, Achievements, and Impacts

- What are the expected outcomes of the CERSI's academic component (i.e., Master's or other degree programs in regulatory science, lectureships, professional development, and scientific exchange programs)?
- How should the impact of the CERSI academic component be measured?

4. CERSI Administration and Infrastructure

i. Building Effective Public–Private Partnerships

- How can the CERSIs serve as a hub for public–private partnerships to bring stakeholders (e.g., U.S. and international governments, academia, industry, professional and patient groups) together?

ii. Investment and Return on Investment

- Is an initial three-year funding period adequate to support and sustain the establishment of a new CERSI? At what level should FDA support continue beyond an initial funding period?
- Are there potential models to sustain CERSIs other than ongoing FDA support?

iii. Building Synergy among the CERSIs, FDA, and Stakeholders

- What is the most productive model for a network of CERSIs? (e.g., models used by other centers established by NIH, Howard Hughes Medical Institute (HHMI), and Clinical and Translational Science Award (CTSA) institutions) and what can be coordinated or shared among the network of CERSIs?
- What is the optimal size of the CERSI network and why (e.g., 4, 8, 10 institutions or more)?

II. Process

A. Subcommittee Formation and Review of Materials

The Subcommittee was officially established by memo in January of 2015 and the full membership was on board in April 2015. The Subcommittee was composed of the following members:

Sherine E. Gabriel, MD, MSc
Dean and Professor of Medicine
Rutgers-Robert Wood Johnson Medical School
CEO Robert Wood Johnson Medical Group
Emeritus Professor of Medicine
Mayo Clinic

Rebecca Jackson, MD
Associate Dean for Clinical Research in the College of Medicine, Professor of Medicine, and Director, Center for Clinical and Translational Science
The Ohio State University

Emma Meagher, MD
Senior Associate Dean for Clinical Research, Chief, Clinical Research Officer, Associate Vice Provost for Human Research, and Director, Translational Research Education
Hospital of the University of Pennsylvania

Robert J. Meyer, MD
Director, Virginia Center for Translational and Regulatory Sciences
Associate Professor, Public Health Sciences, School of Medicine
University of Virginia

Amy Patterson, MD
Director of Scientific Research Programs, Policy, and Strategic Initiatives and Chief Scientific Advisor
National Heart, Lung, and Blood Institute
National Institutes of Health

Robert W. Pinner, MD
Associate Director for Programs, Surveillance and Informatics
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Theodore F. Reiss, MD, MBE
Science Board Member
Head, Clinical Research and Development, Inflammation and Immunology
Celgene

Michael Rosenblatt, MD
Executive Vice President and Chief Medical Officer
Merck & Co., Inc.

Scott J. Steele, PhD
Subcommittee Chair
Director, Government and Academic Research Alliances, Deputy Director, Goergen Institute for Data Science, and Associate Professor, Public Health Sciences
University of Rochester

Laura L. Tosi, MD
Science Board Member
Director, Bone Health Program
Department of Pediatric Orthopaedic Surgery
Children's National Medical Center

The Subcommittee held a kickoff call in April 2015. It began monthly calls to review the charge as well as a series of background materials on the CERSI program and each of the four CERSI awardees. A resource table was used to categorize resources and background materials that aligned with each of the four areas or domains of the charge. Requests were made for these and a range of other background materials, and the ORSI staff assisted with providing this information, along with previous Science Board reports, strategic plans, and other relevant materials. Subcommittee leads were identified for each of the four domains outlined in the Charge while the entire Subcommittee participated in the review and evaluation of the CERSI program.

B. Site Visit

Before the site visit, the Subcommittee asked that each of the four CERSIs and the members of the FDA CERSI Steering Committee(s) conduct a Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis to aid the Subcommittees review and to inform the discussion during the site visit. These assessments proved invaluable for our review and assessment. Additionally, the Subcommittee provided a series of questions to consider in advance of the site visit, along with the Charge to the Subcommittee.

The site visit was held on October 1–2, 2015, at FDA (White Oak) and included a series of meetings with FDA leadership, principal investigators (PIs), and key personnel from each of the four CERSIs, members from the FDA CERSI Steering Committee(s) and Senior Science Council (SSC), as well as leadership and key staff from the Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), and the Center for Drug Evaluation and Research (CDER). The full agenda is included in Appendix A. The site visit was an essential component of the review and provided substantive and valuable insights, along with productive discussions with key individuals involved with the CERSI program.

III. Key Findings

The following key findings based on the review and site visit are generally categorized according to the domains outlined in the Charge to the Subcommittee.

Context

The Subcommittee recognizes that the CERSI program represents one program in a broader set of initiatives across FDA to advance regulatory science. In addition to scientific challenges, FDA efforts to advance regulatory science are also affected by broader non-scientific issues of human resources, funding for training, as well as time and incentives for FDA staff to participate in these initiatives. Although many FDA staff members find it professionally rewarding to participate in regulatory science development, they indicated that their engagement is hampered by FDA's significant routine regulatory workload. The roughly 1,500 vacancies at FDA, including in key review and scientific positions at FDA product centers (e.g., more than 600 staff vacancies at CDER), surely contribute to staff's reluctance to participate. CERSIs were in part created to support FDA external collaborations. However, FDA scientists and reviewers face travel restrictions and very limited funding for all training, travel, conferences, and related expenses.

A. Findings Based on Meetings with FDA

Based on discussions with leadership from several FDA centers and major offices, there is general support across FDA for engagement with external partners on regulatory science-related research, with tepid interest for education and training opportunities. However, overall there was little enthusiasm for the CERSIs as the appropriate mechanism. Most—if not all—centers appear to prefer to drive these collaborations through other mechanisms, often building on existing research collaborations or new external partnerships that address their specific needs. The value of the CERSI educational programs to the centers was particularly unclear, based on the centers' feedback.

A.1 Diffuse Mission and Lack of Specific Objectives Make Assessment a Challenge

Although FDA's ORSI is a vital advocate for the CERSI program and has made laudable efforts to support and expand the program, the CERSIs' diffuse mission and goals make it difficult to assess progress and for FDA centers and offices to know how to best engage with the CERSIs. The CERSI program's ambiguous goals, limited funding, and sometimes specialized areas of expertise within individual CERSIs add to the challenge.

The resulting questions raised by the Subcommittee include: Are CERSIs designed to address FDA regulatory science needs specifically, broader societal needs, or both? How do activities align among CERSIs for synergies and/or integrate with efforts of the NIH Clinical and Translational Science Award (CTSA) Consortium?

A.2 Limited Engagement with Centers

Based on meetings with FDA leadership and staff during the site visit and through written responses, it became evident that the FDA centers were not effectively engaged in the original development of the CERSIs, their strategic research agendas, or the selection of institutions. Although the current CERSIs are among the leading academic research institutions in the nation, it remains unclear whether their strengths specifically match FDA's highest needs and most significant science gaps. This fact impairs the Subcommittee's ability to provide specific recommendations on how to best structure the CERSIs to address FDAs needs.

FDA center engagement with the CERSI has increased over time, but remains variable by center and still poses a challenge. There was a notable difference in the level of engagement across the Agency between the first round and second round of the CERSIs, but this may be largely the result of pre-existing relationships with the awarded institutions. In either case, there remains significant ambiguity and heterogeneity between the different CERSIs and their level of interactions with different FDA centers.

The CERSI program could be significantly improved by having a clearer articulation of goals and purpose, with improved coordination and communication processes within FDA and between FDA and the CERSI institutions. Specifically, a shared commitment and vision between the Commissioner's Office and FDA centers and major offices is needed. For instance, it is not evident to the Subcommittee whether the CERSIs' primary goal is to meet FDA needs or to address the needs of the academic institution (or national needs). This should be clarified, particularly given the limited funding available for the CERSI program and the requirement to set priorities. A critical FDA-wide issue is the lack of a needs assessment or roadmap for FDA regulatory science research and education/training.

A debate also exists between a top-down versus bottom-up approach for broadly facilitating FDA engagement with academic institutions and identifying specific projects, where many FDA centers already have very successful existing partnerships. Related to addressing FDA project needs, an alternate approach may be to view and select CERSIs as platforms of capabilities that can then address specific project needs as they are later identified versus being selected based on proposed projects defined a priori as meeting

FDA's needs at the time of the Request for Applications (RFA). The advantage to the "platform" approach is flexibility to meet FDA needs as they arise.

Finally, the Reagan-Udall Foundation (RUF) has unmet potential to support a range of regulatory science activities, and effort should be made to leverage this potential. Coordination of activities with the RUF, as it grows and matures in its funding of regulatory science projects, offers important opportunities. Failure to effectively integrate RUF activities, the Clinical and Translational Science Awards (CTSA) Consortium, and the CERSI program may represent a missed opportunity to enhance efficiency and limit redundancy.

B. Findings Based on Meetings with the CERSIs

The CERSI award helped change or enhance the culture at some of the CERSI institutions by raising awareness of the significance of regulatory science, the critical need for research and education in this area, and the opportunities regulatory science offers as an attractive career path.

B.1 Divergent Views of Approach and Mission

Individual CERSIs have different views of the CERSI program's approach and mission. Specific examples of this divergence include views about how to identify research projects, the use of Public–Private Partnerships (PPPs) as a means of sustained funding, and the types and forms of education and training programs. Some of this variation is tied to cultural/geographic considerations and the result of existing structures developed before receiving the CERSI award. Elements of this diversity can be a strength, in some cases, but also a challenge in the absence of FDA's clear priorities and active planning and portfolio management to limit duplication and encourage synergistic activities that address FDA needs.

Areas of focus for the CERSIs continue to evolve over time, partly linked to emerging funding opportunities (e.g., Office of Minority Health awards) and the stage of their FDA support. For example, newer CERSIs are ramping up activities (e.g., UCSF-Stanford) while the older cohort is reducing research activities (e.g., M-CERSI). The CERSIs also have taken different approaches to including or affiliating other programs at their institutions with their CERSI, which also contributes to variability.

Concerning PPPs, some CERSIs are very wary of industry partnerships while others actively develop entrepreneurial partnerships with industry. Limitations in achieving robust PPP financial support are in part due to restrictions in the original award that limited CERSIs' ability to raise extramural funds (subsequently rectified), but there are also cultural differences among the CERSIs beyond these original limitations.

B.2 Uncertain Value for the CERSI Network

Since the CERSI network concept is still in its infancy, the Subcommittee did not evaluate the effectiveness of the current network but focused on the network concept, its potential benefits, and what the network would accomplish. At this early stage, the value for the CERSIs as a network remains unclear, particularly because of the lack of a coherent overarching mission and objectives. Current benefits of forming a network seem to focus on sharing best practices and lessons learned between the individual CERSIs. But internally, FDA needs to share best practices and key learnings about the CERSI program across the four FDA CERSI Steering Committees.

The increased geographic distribution, with the addition of the UCSF-Stanford CERSI, appears to have several strengths (e.g., leveraging regional scientific prowess and capabilities). However, with the broad mission and diverse expertise among the CERSIs, collaboration and synergistic opportunities are challenging. In reality, given the funding constraints, there is increased potential for competition, rather than collaboration, between the CERSIs. If the CERSIs focused on complementary areas of expertise linked to a more focused research and educational agenda, a network approach would be more valuable and make opportunities for engagement more transparent for FDA.

B.3 Challenges with Sustainability

There was consensus from the CERSIs that the original model for achieving sustainability by year three is not feasible. Three years is insufficient for academic institutions to achieve the maturation efforts that would be foundational to creating a sustainable business model, since potential partner organizations expect a record of achievement. Recognizing this, FDA has provided supplemental/bridging funds and a renewal process for the original CERSIs (albeit at a much lower funding level). Indeed, if FDA were to withdraw its funding entirely at three years, it is doubtful a CERSI would survive as a stand-alone entity, let alone continue to contribute to FDA's evolving regulatory science agenda. Furthermore, the realities of academia mean that a continued partnership between FDA and CERSIs requires continued Agency funding as an incentive for the CERSI activities to stay aligned with FDA's regulatory science agenda (the Subcommittee identified cases where the CERSIs had projects evolve from addressing FDA needs to their own academic needs, in part tied to sustainability). However, such sustained relationships would also require selecting projects based on a systematic needs assessment from FDA to identify a roadmap for education and research.

C. Research

C.1 Challenges to Identify and Address FDA Priorities

Each of the CERSI institutions is a highly capable research university with extensive research expertise relevant to FDA. Each institution can provide access to unique facilities and research infrastructure. One of the obvious challenges for best using the CERSIs is finding the optimal approach to identify FDA's research needs and regulatory science gaps to inform specific project proposals. This was particularly challenging for the original CERSIs, given the nature of the RFA released for the initial round.

The CERSIs have employed different processes in getting to specific research proposals. These differences are due in part to changes from the first round of awards to the second, in some cases using more of a joint FDA-CERSI workshop format or soliciting calls for proposals and then having FDA review the topics. Many of the focus areas have concentrated on expanding existing collaborations or projects that build on the CERSI PIs' previous work (see below).

Significant opportunities exist to engage other researchers and further interlink research and educational elements within a CERSI. For instance, post-graduate students in regulatory science training programs could participate actively in the institution's research projects as a part of their training. Currently, most of the research projects appear divorced from any project work of the students in the CERSI.

During the site visit, the Subcommittee heard dissatisfaction from some FDA staff about the predominant "top-down" approach used to identify research priorities and projects (versus first seeking input from staff-level scientists). There is also tension between ORSI staff's identification of research areas instead of center-level determination of research areas that would support new research or expand existing research projects and collaborations.

Additionally, many individual scientists and reviewers throughout FDA centers and offices have existing well-established collaborations with non-CERSI academic institutions and specific projects may then get funded by other means, such as using a Broad Agency Announcement (BAA). While there have been recent examples of increased responsiveness to emerging opportunities from FDA centers and offices, this remains a key strategic issue.

C.2 Level of Resources Necessitates Leveraging Existing Projects

The limited resources provided to the CERSIs to achieve the ambitious regulatory science research goals, while also developing an educational program, require that they leverage existing projects, expertise, and infrastructure rather than create wholly new offerings. This restriction presents a significant challenge in aligning the research projects with the scientific priority areas FDA has identified, particularly since Agency priorities and needs may change over the course of a CERSI cycle.

C.3 Access to FDA Data

Individuals who are not FDA employees or FDA contractors face substantial legal constraints in accessing FDA data and information that are not in the public domain. This represents a challenge for FDA research collaborations with the CERSIs since the way the CERSI U01 cooperative agreement is structured presents hurdles to data-sharing that do not exist with a contract mechanism.

To resolve specific data-sharing challenges, in some cases, CERSI researchers have been supported by a contract, such as a BAA. In these situations, the CERSI researchers may access FDA data since contractors may have access to FDA confidential information under the Food, Drug and Cosmetic Act. However, some FDA centers expressed a desire to have research collaborations with the CERSIs that allow access to confidential information via a cooperative agreement mechanism, as opposed to a contractual relationship. Note that RUF fellows have access to confidential information under the same legal provisions for FDA contractors. However, RUF's ability to bring CERSI researchers into FDA has not been achieved, in part, due to funding considerations since the RUF does not currently have the means or infrastructure to support fellowships.

C.4 Project and Portfolio Management

Overall, the CERSI research lacked effective project management, particularly broader portfolio management of research activities across the CERSI program. This was partly due to the processes used in selecting the original CERSIs and prioritizing projects.

Some of the original research projects also lack clearly defined desired outcomes, deliverables, and assessment of scope. This limits the ability to judge the success and impact of these projects. There also does not seem to be a robust, transparent, and iterative process to refine projects as needs and knowledge evolve. The FDA centers did not have an active role in identifying and selecting most of the CERSI projects, though FDA centers are increasingly engaged in project management. Although separate FDA CERSI Steering Committees were established for each CERSI (albeit with significant

overlap in membership), the steering committees should have an increased role in identifying and vetting research priorities and overseeing progress.

Additionally, FDA-only planning meetings between the Steering Committees should be organized to discuss FDA needs and priorities and to review the broader CERSI research portfolio. This could help limit redundancy and maximize impact and alignment with other intramural and extramural projects, as well as provide for a better sharing of best practices across the program. The level of engagement between FDA and the CERSI institutions also appears to present a challenge. Although there was an effort to ensure a level of independence and flexibility at each CERSI, there also seemed to be limited project management from some critical FDA centers and offices.

D. Education

D.1 Limited Alignment between FDA Training and Workforce Needs and CERSI Programs

There is no apparent cohesive vision of FDA's training and education needs and gaps, or how the CERSIs might best address these needs. This includes regulatory science educational training of FDA's current workforce as well as educating and attracting its future workforce through formal course work/degrees and other training opportunities (e.g., workshops and exchanges). There was no initial roadmap for training needs, and the CERSIs education programs were not necessarily designed to address FDA needs.

Given that the CERSI program's role in meeting educational needs and goals was never clearly defined, each CERSI understandably interpreted the educational component differently across the CERSI program, and the CERSIs and FDA are not clearly aligned on educational initiatives. For example, FDA indicated less interest in CERSI's establishing formal regulatory science degree programs because they most value new employees having advanced degrees in their specific areas of scientific expertise (e.g., a PhD in statistics). Yet several CERSIs have developed formal degree programs that they view as complementing their existing programs and addressing a national need. Some CERSIs also view these educational programs as important for their program's financial sustainability.

It appears that FDA has a greater internal need for CERSIs to conduct targeted workshops, seminars, individual courses, and exchanges rather than formal study programs. Several FDA centers indicated that although core expertise in key technical areas (e.g., statistics, toxicology, and epidemiology) is a base line requirement for new scientific staff, additional regulatory science competencies and hands-on training experiences would decrease the learning curve and help ensure trainees' commitment

to this field of work. Nevertheless, there was debate within FDA about the value of a candidate's having a formal MS degree or even a certificate in regulatory science. Although the initial CERSI education programs may address industry or academic translational research needs, they are not necessarily addressing specific FDA needs. Hence, early CERSI programs and competencies under development or being offered are potentially misaligned with FDA's needs and would benefit from clearer expectations of the educational efforts in the CERSI program.

D.2 Difficulty Placing Scholars at FDA

In the training area, the CERSIs' most significant obstacle is placing trainees at FDA for an experiential opportunity, particularly providing an experience in regulatory review. This is largely due to limitations in access to confidential commercial information (CCI). These legal limitations are appropriate to safeguard such information and the review process, but are not being creatively addressed to promote flexibility in hosting trainees at FDA (even for the CERSIs). Yet, as FDA faces challenges in filling its scientific workforce pipeline and as awareness and interest in a regulatory science career path grows, trainees would benefit greatly from hands-on experiences at FDA, as well as within industry and academia. Although not providing opportunities for regulatory review, the Subcommittee was encouraged by the development of fellowship programs by the GU CERSI[1]and the UCSF-Stanford CERSI[2] .

D.3 Access and Sharing of Course Work

Sharing of coursework remains a problem between CERSI institutions and FDA, while tuition reimbursement is a key barrier for FDA staff participation. Additionally, some Maryland policies (see Maryland requirement) create financial and administrative requirements for out-of-state institutions to have their on-line courses registered. This can further affect access to on-line courses for FDA staff living in Maryland. Although JHU offers education to FDA for the Commissioner's Fellowship program, this is remunerated and preceded JHU's CERSI designation.

D.4 FDA Staff Time and Incentives for Training and Professional Development

FDA scientists and reviewers ultimately have limited time, funding, and incentives to participate in programs the CERSIs offer. Thus, many FDA scientists revert to long-standing collaborations with other organizations or institutions that offer training and professional development over new engagements with CERSIs. One of the more

[1] Georgetown University-PhRMA Foundation Fellowship in Regulatory Science, Available at: http://regulatoryscience.georgetown.edu/RS-fellowship. Accessed on February 11, 2016.
[2] UCSF-Stanford CERSI Postdoctoral Fellowship in Regulatory Science. Available at: https://pharm.ucsf.edu/cersi/node/3781. Accessed on February 11, 2016.

proactive programs for involving FDA scientists is the UCSF-Stanford CERSI, but its geographic distance from FDA headquarters (requiring travel costs) is a consideration, given the limitations on FDA staff travel and training.

E. Administration and Infrastructure

E.1 ORSI Contribution and FDA Engagement

ORSI has shown significant commitment, energy, and enthusiasm in its support of the CERSI program. Nevertheless, a disconnect remains between ORSI and the centers that the Subcommittee finds hinders progress and impairs the CERSI program's impact. Although there appear to be different levels of internal FDA coordination among the FDA Senior Science Council and four FDA CERSI Steering Committees, significant challenges remain to ensuring broad and effective FDA engagement.

E.2 Project Management and Governance

Internal communication challenges and lack of clear priorities for the CERSIs are mirrored in the CERSI program's project management and governance. In particular, the role of the ORSI staff and that of the FDA centers is vague at times and not necessarily standardized between FDA CERSI Steering Committees, other than some shared personnel at FDA.

E.3 Duration of Funding and Long-Term Engagement

As previously noted, the original plan to fund the CERSIs for three years falls short of what is needed to carry out the CERSI mission and to conduct planning activities. This is not a failure of the existing CERSIs; it is the reality of building a novel academic enterprise. The Subcommittee noted the impact after funding changes, where some research programs were reduced or eliminated. Indeed, the CERSI PIs acknowledged their CERSI would largely disappear without FDA support, or fold back into existing programs. Given the three-year timeline, individual research efforts also face challenges that reflect the uncertainty of future funding and continuing FDA commitment to the projects.

Some CERSI PIs were very enthusiastic about the CERSI award's impact and were able to obtain leadership buy-in at their institution, but the limited budget at some of the CERSIs was a problem. It is not always clear whether the rationale behind the significant variability in funding of the different CERSIs was the result of strategic or opportunistic decisions based on the availability of funding (though it appears to be the latter).

E.4 Role and Potential for CERSI Network and Broader Partnerships

The potential benefit of a CERSI program that operates as a collaborative network remains open to question. Although there may be value in the institutions' diverse strengths and geographical locations, the program's lack of a clearly articulated mission and scope remains an issue. The primary value in the network as it currently exists appears to be in sharing best practices between the grantee institutions. Ideally, there should be more complementary expertise and interests between CERSIs, and shared goals would help limit potential competition and encourage collaboration.

Increased specialization within the CERSIs with complementary areas of expertise could lead to more collaboration and give FDA a better mechanism to identify matching interests and needs. But, as previously mentioned, without an overarching CERSI program mission, it is hard to evaluate the potential value of an interface and alignment with the CTSA Network, other Academic Medical Centers (AMCs), and related governmental and nongovernmental networks in addressing broader regulatory and translational science needs.

E.5 Nature of Agreement

The U01 cooperative agreements (versus contracts) appear to work well for developing research and education collaborations, but this structure provided data-sharing challenges and initial barriers for supplemental support from other centers, Federal agencies, and the private sector. While the barriers to pursuing additional funding support have been resolved, a range of real and perceived obstacles to data-sharing remain.

E.6 Outcomes

The Subcommittee was impressed by many of the individual CERSI accomplishments. However, assessing whether these are individually or holistically making an impact, given FDA's expenditure in time and budget is not possible. To do so would require a clearer definition of the CERSI program's core intent, along with clear metrics for the desired outcomes.

IV. Recommendations

Preamble and Context

The Subcommittee recognizes that the CERSI program was launched as an experiment, an initiative among a broader suite of FDA initiatives to advance regulatory science. As part of the learning process, there are several lessons that can be integrated to provide a crisper focus for regulatory science initiatives moving forward. Having been invited by FDA to review the first phase of the CERSI program, the Subcommittee notes several challenges to evaluating the impact of the CERSI program in helping FDA to achieve its aims in regulatory science education and research. The Subcommittee recommends a clearly articulated vision for the CERSIs, as well as specific and aligned objectives with metrics for success developed with and communicated across the Agency. This will also provide key elements for any future evaluation of the CERSI program, as one element of several programs to advance FDA's broad regulatory science needs. While beyond the FDA's purview, we would urge Congress to increase support for FDA's regulatory science initiatives, given their critical role and limited funding[3].

… the Subcommittee recommends a clearly articulated vision for the CERSIs, as well as specific and aligned objectives with metrics for success, developed with and communicated across the Agency.

As a first recommendation noted above, we suggest that, if FDA believes the concept of the CERSIs is valuable, FDA leadership (ORSI and center leadership) should articulate a clear, defined vision, mission, and objectives for the CERSIs as a program. The Subcommittee then recommends addressing the cross-cutting areas below and the more specific recommendations that follow.

Cross-Cutting Areas

A. Develop an FDA Regulatory Science Research and Education Roadmap

FDA should conduct a coordinated end-to-end needs assessment (or roadmap) that would guide the Agency's specific regulatory science research and education priorities and requirements (including developing external partnerships). This will drive the selection of more expansive external partnerships, including the choice of specific CERSI

[3] Note: Federal members of the Subcommittee withheld comment on this suggestion.

institutions and the desired expertise, research projects, and educational initiatives. This roadmap should be linked to a broader FDA regulatory science communication plan, further clarifying FDA's regulatory science goals and the value of regulatory science to a range of key partners.

B. Define the Scope of the CERSI Program

The scope of the CERSI research and educational activities needs to be further defined. Although broad priority research areas were selected from existing FDA scientific priorities, debate remains about whether priority areas, such as food and tobacco, that have existing academic centers of excellence established by FDA product centers, should also fall under the domain of the CERSI program. Given the existing center of excellence programs in these areas, it would appear that areas of regulatory science related to food and tobacco should fall outside the domain of the CERSIs, particularly considering the limited funding available for the program. FDA should clearly articulate the CERSI program's scope and give a transparent rationale for it.

C. Consider CERSI Selection Based on Broad Capabilities

In considering the roles for the individual CERSIs and the potential value of a network, there were conflicting perspectives on the CERSIs. Should they (1) serve as broader platforms/capabilities with distinct technical expertise and resources to address a range of future research questions (the approach taken with the more recent CERSIs) or (2) be primarily project-driven around more specific research projects (the apparent model for the original CERSI RFA)?

In either scenario, the CERSIs should be more targeted with complementary expertise if there is to be any value of the CERSIs performing as a network. Moreover, since FDA has a BAA mechanism in place to address very specific regulatory science projects, how the CERSI add to or differ from the BAA mechanism is important to articulate.

D. Address Broader Human Capital Considerations

Although particularly relevant to the CERSI program, there are broader human capital issues that FDA should address. Recent FDA Science Board reports[4] have highlighted some of these issues, including the following:

[4] *Mission Possible: How FDA Can Move at the Speed of Science*, Available at: http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/ucm463328.pdf. Accessed on Jan. 29, 2016 and FDA's Commissioner's Fellowship Program, Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM456125.pdf. Accessed on Jan. 29, 2016.

- Barriers to FDA staff participation in training opportunities, scientific meetings, and other professional development activities
- Challenges in placing external scholars at FDA through a coordinated mechanism
- Issues related to data access for scholars and research collaborators
- Overall challenges with the speed and effectiveness of the hiring process
- Pipeline initiatives to recruit, develop, and retain the future workforce

E. Identify Strategic Needs and Establish CERSI Mission and Goals

E.1 Develop a Regulatory Science Roadmap and Strategic Plans

As noted above, a key issue is to clarify the CERSIs' vision, mission, and scope. FDA has identified broad gaps in regulatory science. However, the CERSI program's success requires more specificity and strategic definition. The CERSI program could provide an opportunity for long-term cultural change to bring innovative approaches to addressing emerging topics that have a regulatory science and public health focus while meeting critical FDA needs. Specific recommendations include:

- Address the need for more proactive/preplanning around regulatory science priorities, gaps, and requirements. FDA should launch a collaborative Agency-wide strategic planning and road mapping/needs assessment initiative to identify FDAs regulatory science research as well as technical and education or training needs and priorities. This initiative will create a blueprint for building regulatory science capacity and a network of expertise (beyond the CERSI program) to address emerging questions. This roadmap will also include a dynamic list of specific needs and priority questions. We recommend that this be coordinated by the Chief Scientist, using the Senior Science Council and direct engagement with the center directors.
- Ensure the CERSIs maintain alignment with broader FDA regulatory science initiatives that span FDA centers and major offices.
- Given FDA's strong interest in the CERSI program, there should be a means to increase specific budget amounts to fund the CERSIs. Current funding levels and three-year commitments are infeasible for a broad, effective effort. The Subcommittee recognizes this is only partly under FDA's control, and would require additional appropriations from Congress.

F. Establish CERSI Mission and Goals

The CERSIs should remain both focused on FDA priorities relevant in their functions to FDA, while balancing institutional and external needs. CERSI institutions should provide a platform of expertise and infrastructure, but that institutional expertise should be in

defined areas of specialization and match FDA's stated regulatory science requirements. To this end, selecting CERSIs based on existing capabilities, with specific projects largely identified post-award, is preferable to having projects proposed by the institutions answering the RFA (particularly if the RFA does not have specific research needs for the particular CERSI funding cycle). FDA must also be clear when the use of a CERSI is advantageous versus using other existing or new academic relationships to address a specific need.

G. Provide Active Governance and Portfolio Management

A transparent governance structure and process is required to ensure that the CERSI program's project and portfolio management is effective. This includes developing criteria for selecting CERSI awardees and individual research and educational/training projects. These criteria should consider both the scientific questions facing FDA as well as the scientific expertise and resources available at the CERSI, which could be leveraged in a way that is beneficial to both parties. Metrics for success should be developed and progress against metrics should be regularly reviewed with each CERSI and for the overall portfolio.

G.1 Governance

Without micromanaging daily operations, FDA (ORSI and the centers) need to actively oversee the CERSIs to engage and coordinate initiatives. This would be facilitated if the CERSIs were clearly specialized and aligned with their strengths and FDA priorities. ORSI should engage FDA centers to develop an inventory of priority areas with an active list of potential projects and needs.

G.2 Project Management

Project managers should be identified at FDA and the CERSIs, with ORSI serving as a facilitator and joint project manager and ensuring there is a center-level liaison/project manager at each relevant FDA center or office. ORSI should serve as a facilitator between FDA centers and CERSIs to help identify and coordinate lists of potential projects. Projects should have clear definitions, a scope assessment, achievable deliverables, and relevance for FDA. These should be outlined in a project management plan with clear milestones, metrics, and contingency plans. Project shaping will enable projects to be further modified through an iterative process with FDA.

G.3 Portfolio Management

Research and educational initiatives at each CERSI should also be reviewed as part of a broader portfolio management initiative, to review and pro-actively manage activities

across the entire CERSI program. This approach should be taken for both research projects as well as the education and training portfolio.

The portfolio review should consider activities across the CERSIs, as well as a broader review of other FDA extramural programs, NIH programs, and other national initiatives addressing regulatory science priorities. This review will be critical in setting priorities, identifying areas for collaborations, and avoiding unnecessary duplication. For example, the CERSIs do not currently concentrate on food, tobacco, and some other FDA priority areas but these areas are addressed through other centers of excellence (e.g., Center for Food Safety and Nutrition Centers of Excellence, and Tobacco Centers of Regulatory Science). We recommend that the CERSI program focus on areas of FDA regulatory science outside of those with existing effective FDA programs and collaborations. FDA's Senior Science Council can offer a mechanism to provide strategic level advice on priorities and other related extramural programs to assist with effective portfolio management and improved coordination.

H. Improve Coordination, Communication, and Collaboration at All Levels

H.1 FDA Coordination and Communication

While the FDA Senior Science Council and the four CERSI Steering Committees represent an opportunity for communication and coordination, they have not been effective in clarifying the CERSI program's vision and ensuring support across FDA. The Senior Science Council should help inform and coordinate strategic priorities and the CERSI program's scope, but representatives must have clear authority to represent each center director on these matters, ensuring improved interaction between the OCS and the centers.

The four FDA CERSI Steering Committee(s) should be integrated into one FDA CERSI Steering Committee, with a clear charge to help establish a collective direction. There is significant overlap between the four current Steering Committees and the membership. A new single integrated Steering Committee should be further reviewed to ensure appropriate representation across the centers and other offices, while maintaining a group that is highly functional.

Some participants may be included on an ad hoc basis depending on the topic (and if the CERSIs become more specialized/targeted), while others are core members based on the broader research and training initiatives. The new integrated FDA CERSI Steering Committee should hold internal FDA meetings to proactively coordinate specific plans, priorities, and provide active oversight. The Subcommittee was encouraged by ORSI's

recent effort to bring together the four Steering Committees to coordinate workshops and fellowships, and believe the proposed integrated FDA CERSI Steering Committee will further streamline these efforts.

I. Address Barriers to Access FDA

One of the key barriers to advance training is the actual and perceived legal and policy obstacles that make placing trainees at FDA a challenge. FDA should explore mechanisms and policy issues to implement more flexible approaches to placing scholars at any level (graduate students to later-career sabbaticals) at FDA. This is a particular issue for work involving regulatory review and access to CCI.

It is essential that FDA resolve this issue, not only to increase its scientific workforce pipeline but to raise awareness and interest in regulatory science. Some programs, such as the Commissioner's Fellowship program and statutory authority for the RUF, enable access to CCI. Creating a broader umbrella framework to coordinate fellowships/traineeships may be a way to resolve this issue[5]. Although a defined funding structure would be required to achieve this, RUF could serve as a potential coordinating mechanism for fellows in a review track, using existing legal mechanisms to recruit and place scholars. OCS should identify and implement specific approaches to address this critical issue, using a broader umbrella to coordinate existing fellowship programs, where appropriate. This should also be linked with efforts to provide diverse regulatory science training opportunities across multiple sectors.

Data-sharing and access to FDA data remains a challenge for productive research collaborations. This area should be further addressed. While RUF may be one pathway to do so, the Subcommittee recommends internal discussions with FDA to creatively tackle other means of enabling sharing of FDA-held data, understanding the considerable legal hurdles in doing so. This includes clarifying perceived versus actual barriers.

J. Improve Coordination and Sharing of Educational Resources

One challenge with regulatory science training has been the difficulty in defining "regulatory science" and the associated competencies. A set of regulatory science educational competencies have recently been developed as a broad template to guide training and education in this area[6]. These and other resources could be used as an

[5] FDA's Commissioner's Fellowship Program, Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM456125.pdf. Accessed on Jan. 29, 2016.

[6] Adamo JE, Wilhelm EE, Steele SJ. Advancing a Vision for Regulatory Science Training. *Clin Transl Sci.* Oct 2015;8(5):615-618.

initial template to communicate and align baseline competencies (or knowledge, skills, and abilities) across CERSIs and as a means to align and engage CTSAs, other AMCs, foundations, and societies. This approach could provide a common framework and language to communicate current resources, programs, and needs.

Some barriers continue to exist regarding the availability of educational resources. A requirement should be included that any case studies, materials, or other educational resources developed through FDA funding (including CERSI grants) should be made publicly available. To improve efficiency in sharing these education and training resources, a more centralized educational portal should provide links to these resources. If an existing portal cannot be used, a new portal should be established, closely collaborating with the RUF, CERSIs, and the CTSA Network.

K. Develop Metrics Based on CERSI Program Objectives and Re-evaluate CERSI Program

Specific goals and objectives for the CERSI program are required to develop associated metrics. Periodic program evaluations should be conducted based on these defined goals and measurable outcomes, with a periodicity approximating the funding cycle. The specific outputs and deliverables will be tied to a clear mission and objectives, and further aligned to areas of focus for each CERSI.

The new FDA roadmap for research and education and training should also tie new metrics measuring impact on new guidance, development of new reviewer tools, changes in processes, targeted training offerings, responsiveness to FDA requests, and other areas directly affecting FDA. The revamped CERSI program should reflect the new metrics and design in the collection of these deliverables.

L. Create an Effective CERSI Network and Collaborations among CERSIs, FDA, Industry, and Academic Partners

L.1 Establish a Small, Targeted Network that Leverages Partners

A productive CERSI Network should be tied to a clarified mission and scope, with CERSIs having a more specialized focus that provides complementary areas of expertise. The refined scope and objectives for the CERSI program will determine the rational funding level for the overall program and individual CERSIs. We might envision a small, targeted, and nimble network of four to eight CERSIs that also engage the CTSA Consortium, RUF, industry and others on regulatory science initiatives and the broader innovation process as a force multiplier. This would also provide shared funding mechanisms and enable expansion in some priority areas, with FDA only providing a base level of sustained funding, after an initial full funding period of five years for a new CERSI. Additionally, targeted BAAs from FDA centers and other sources (e.g., NIH, PCORI, PPPs) for other projects provide opportunities for supplemental funding in aligned areas.

This small number of CERSIs (four to eight) could serve as a network to pilot regulatory science initiatives for FDA. The priorities for the CERSIs would include:

- Development of novel methods, models and research tools
- Designing new training approaches and programs

Best practices in these areas are collated and disseminated to the CTSA Consortium, AMCs and other stakeholders, with support from the RUF.

The CERSIs should also build essential PPPs for research and education. These can take the form of research collaborations, advisory roles, student opportunities, and potential financial support. These partnerships are meant to augment, not replace, FDA engagement and support. A clear scientific connection to FDA and steady state funding is essential to drive FDA-specific projects, while other sources of funding should be identified, including FDA center support and PPPs. There is clearly a role for RUF in developing and supporting PPPs and this should be further pursued as the RUF evolves in its capabilities and funding.

Fostering collaborations between FDA and the CERSIs will require improved incentives for FDA scientists and reviewers to engage with CERSIs, while also supporting opportunities for broader scientific and professional development. Encouraging collaborations with the CERSIs should not detract from maintaining existing productive academic collaborations developed by FDA centers. An event should be organized with intramural FDA participation, CERSIs, CTSAs, and RUF to enhance collaborations. This

event could be held every other year by the OCS and alternate with the joint ORSI and FDA Science Forum event. Such an event could be also be launched using the convening power of the RUF.

L.2 Balance the Network Size and Broader Regulatory Science Funding Requirements

The size of the CERSI Network must also be balanced with overall OCS/ORSI resources to ensure that all CERSIs have a steady state level of sustained funds from FDA. This will ensure that the CERSIs are addressing FDA-specific requirements and will maintain continued engagement with FDA.

This process would use a coordinated approach within FDA and the roadmap outlined previously. Given limited resources, it would be better to ensure continued support of a smaller number of existing CERSIs versus launching an expanded CERSI network without some level of continued support from FDA to sustain this resource.

Ideally, FDA would be able to direct much more robust funding to their regulatory science needs. However, the Subcommittee recognizes that this is largely outside of FDA's purview and depends on directed appropriations.

More broadly, the budget and time constraints on FDA staff's ability to travel to conferences and participate in any scientific exchanges and external research collaborations is a fundamental issue. We also recognize that this too is only partly under FDA's direct control, but believe this is a significant gap and priority that must also be tackled and balanced against any potential expansion of the CERSI program.

Appendix A: CERSI Program Evaluation Subcommittee Site Visit Agenda

Thursday, October 1, 2015, 7:30 a.m. — 6:00 p.m.
FDA White Oak Campus—Building 22, Room 1415

7:30 - 8:00 a.m.	Intro/overview of tasks for meeting, orders for lunches
8:00 - 8:30 a.m.	**Meeting with Dr. Stephen Ostroff** Acting Commissioner, FDA
8:30 - 8:45 a.m.	Break
8:45 - 9:15 a.m.	**Meeting with Dr. Karen Midthun, Director** Center for Biologics Evaluation and Research (CBER)
9:15 - 9:30 a.m.	Break
9:30 - 10:00 a.m.	Meeting with Dr. Robert Califf Deputy Commissioner for Medical Products and Tobacco (*teleconference*)
10:00 - 10:30 a.m.	Break
10:30 a.m. - 12:30 p.m.	Meet with Georgetown University (GU) CERSI
12:30 - 1:00 p.m.	Break and box lunches delivered
1:00 - 2:30 p.m.	University of California - San Francisco (UCSF) - Stanford University CERSI (*video-teleconference*)
2:30 - 3:00 p.m.	Break
3:00 - 5:00 p.m.	Meet with University of Maryland (UM) CERSI
5:00 - 6:00 p.m.	Committee Session/Writing Session

Friday, October 2, 2015, 7:15 am - 3:30 p.m.

7:15 - 7:45 a.m.	Overview of tasks for meeting, orders for lunches accepted
7:45 - 8:15 a.m.	Meeting with Dr. Carol Linden and Dr. Frank Weichold, ORSI
8:15 - 8:30 a.m.	Break
8:30 - 10:00 a.m.	Meeting with FDA CERSI Steering Committee Members
10:00 - 10:30 a.m.	Break
10:30 a.m. - 12:00 p.m.	Meeting with Johns Hopkins University (JHU) CERSI
12:00 - 12:30 p.m.	Break
12:30 - 1:00 p.m.	Meeting with Dr. Janet Woodcock Director, Center for Drug Evaluation and Research (CDER)
1:00 - 1:30 p.m.	Break and box lunches delivered
1:30 - 2:00 p.m.	Meeting with Dr. Kyle Myers Director, Division of Imaging, Diagnostics, and Software Reliability, OSEL, Center for Devices and Radiological Health (CDRH), on behalf of Dr. Jeffrey Shuren, Director, CDRH
2:00 - 3:30 p.m.	Committee Session/Writing Session (Some members may need to depart earlier than 3:30 p.m.)