Science Looking Forward Subcommittee to the Science Board

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Subcommittee Chair

2007 “Science and Mission at Risk” Report

- Major findings
  - Demands on FDA have soared
  - Resources have not increased

2007 “Science and Mission at Risk” Report

- Major findings
  - FDA cannot fulfill its mission because its scientific base has eroded and its scientific organization structure is weak
  - FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability
  - IT infrastructure is inadequate

Progress Since 2007 – some highlights

- Creation of an “Office of the Chief Scientist”
  - Coordinate and promote regulatory science
  - Oversee professional development of agency scientists
  - Cross-cutting scientific activities
- Senior Science Council
  - Senior science leads from across the agency
  - Over-arching regulatory science priorities

Progress Since 2007 – some highlights

- Office of Foods and Veterinary Medicine
  - Assure greater priority and focus for food-related responsibilities
- New responsibilities
  - Regulation of cigarettes and other tobacco products
  - New food safety system using a science-based approach
  - Expedite review of generic drugs, better protect imported drugs

Progress Since 2007 – some highlights

- Transparency initiative
- Centralized campus with state-of-the-art labs
- Advancing Regulatory Science Strategic Plan

Summary

- The agency has made great strides since the 2007 report
- Common themes remain
  - Increased responsibilities
  - Strain on resources
- For an agency with such great responsibility, it is important to continuously evaluate progress and identify ways to improve

That Brings Us To Our Charge…

- This subcommittee was asked to examine three domains of regulatory science activities to assess progress made since 2007 “Science and Mission at Risk” report
  I. Priorities, Activities, and Emerging Needs
  II. Extramural Programs and Collaborations
  III. Supporting an Environment of Scientific Excellence (Workforce)

How Are We Going About It?

- Reviewed a lot of literature
  - Provided by the agency
  - Available publicly
  - Including the “Science Moving Forward” progress report that we requested, which was released publicly earlier this morning
- Talked to stakeholders

How Are We Going About It?

- Conducted a site visit
- Spoke with virtually all leaders across the agency, as well as everyday employees
  - Including Commissioner, former Commissioners, Center heads, Deputy Commissioners, Workforce leads

Here Is Where We Are…

- Draft Recommendations are complete
  - Important to come up with recommendations that are actionable and implementable
  - The agency can accept challenges
    - After all, it is the premier regulatory agency in the world
    - But, keep in mind with great responsibility comes the need for resources and mechanisms to fulfill those responsibilities
  - Let’s go through the recommendations

Draft Recommendations

- What follows is a list of areas on which we recommend the agency focus…
- Area I
  - Medical Product Innovation
    - Biomarker qualification
    - Clinical trial networks and master protocols
    - Bayesian design
    - Sentinel Initiative
    - Risk-based safety assessments

Draft Recommendations

- Area I (continued)
  - Food Safety and Applied Nutrition
    - Hazard mitigation strategies/preventive controls
    - Behavioral sciences, nutrition initiatives
    - Initiatives to improve
      - Monitoring of consumer exposure to contaminants
      - Screening methods for contaminants
      - Toxicology to predict risk of such contaminants
    - Rapid throughput methodologies and technologies
    - Statistically-relevant sampling schemes

Draft Recommendations

- Area I (continued)
  - Product Manufacturing and Quality
    - DNA technology for vaccine safety, foodborne disease outbreaks
    - Nanotechnology
    - Production of biosimilars
    - Field staff technologies
    - New technologies to monitor antibiotic resistance

Draft Recommendations

- Area I (continued)
  - Modernizing Toxicology
    - Identify and qualify biomarkers of toxicity using latest techniques
      - iPSC, bioimaging, in silico models, organs on chips
  - Leadership and Coordination
    - OCS funding to: coordinate allocation of core scientific capabilities and resources within and across the Centers; modernize toxicology and bioinformatics; and proactively establish collaborative programs
    - Science Board charter – more continued engagement

Draft Recommendations

- Area II
  - Enhance funding
    - Ensure partnerships and collaborations have a means to succeed, either with FDA budget or new appropriations or from other stakeholders
  - Catalyze novel extramural partnerships that support and enhance the agency's mission
    - Work with Reagan Udall Foundation to expand range of FDA activities
    - Partner more aggressively with research universities
    - Seek collaborations with research-supporting foundations

Draft Recommendations

- Area II (continued)
  - Establish a portfolio approach to extramural collaborative alliances
    - Set priority areas and match collaborative projects to strategic goals at the center, office and agency levels
    - Pinpoint existing scientific, technical, or knowledge gaps
    - Consider the needs of the FDA community/constituents
    - Ascertain level of resources required for success
      - Ensure projects have means to succeed
    - Identify key players, champions and decisionmakers

Draft Recommendations

- Area II (continued)
  - Establish a portfolio approach to extramural collaborative alliances (continued)
    - Use appropriate project mechanisms (RUF, BAA, etc.) for implementation
    - Review portfolio systematically for balance and impact
    - Weed out obsolete projects, and ensure input from internal and external stakeholders is considered
  - Resource mobilization
    - Recruitment and retention
    - Funding for research and collaborations
    - Access to information

Draft Recommendations

- Area II (continued)
  - Address real or perceived structural hurdles
    - Includes legislative, policy, authority, COI
    - Identify internal policies/procedures that hinder expansion of scientific reach through collaborations
    - Set legislative strategy to address barriers
    - Educate stakeholders on agency's capabilities and partnership opportunities

Draft Recommendations

- Area III
  - Recruitment and Retention
    - Title 38 and 42
    - Direct Hire Authority
    - Special pay levels
    - Merit awards
    - COI nuances
  - Professional education and needs of staff
    - Professional conference attendance
    - Encourage scientists to present research
    - International conferences

Draft Recommendations

- Area III
  - Professional education and needs of staff (continued)
    - Encourage publication in peer-reviewed journals
    - Collaborations with academic institutions to improve training
  - HR and Ethics
    - Need more flexibility in recruitment, purchasing, and awarding of travel privileges

Discussion

- Any comments or questions from the rest of the Science Board?

What's Next?

- Finalize our recommendations
- Finalize our report
  - For release in September

Special thanks to the subcommittee members for all of their hard work, and especially to the subgroup chairs for their leadership.