FDA Science Looking Forward: 5 Years After the Mission at Risk Report

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Subcommittee Recommendations for Strengthening FDA Science

"[t]he demands on the FDA have soared....and the resources have not increased in proportion to the demands."

November 2007, FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology

Recommended:

1. Strategic leadership, support, new resources
2. Focus on emerging science and technologies
3. Strengthening professional development
4. Focus on information technology

FDA Actions

- Broadly advocated for and defined role and importance of regulatory science
- Expanded efforts to support science at FDA
- Promoted scientific collaborations within Agency and with range of stakeholders
- Sought and received first direct appropriation supporting regulatory science and additional resources for targeted regulatory science activities through Medical Countermeasures initiative (MCMi) in 2011

FDA Response to Subcommittee Recommendations, *cont.*

Most change has been through strategically focusing existing resources through enhanced collaboration, leadership, and staff support.

Such activities have included:

1. Creation of Office of the Chief Scientist and Offices of:
   - Regulatory Science and Innovation
   - Scientific Integrity
   - Scientific Professional Development
2. Development of FDA's first Strategic Plan for Regulatory Science
3. Identification in plan of 8 core cross-cutting priority areas
4. Development of strategic science plans and of identified scientific leadership in Centers
5. Dramatic expansion of interagency and external collaborations, focusing on emerging science and technology.

FDA Science: Needs and Opportunities Looking Forward

FDA believes it would now be timely to:

- Report on progress and look forward
- Seek guidance from a new Science Board subcommittee re:
  - Rapidly changing future
  - New leveraging opportunities
- Continue focusing attention on regulatory science challenges/ opportunities, including as critical to FDA's mission to protect and promote public health

FDA Science: Looking Forward

- We propose to seek input in 3 major areas of regulatory science activities relevant to the 2007 report
  - Strategic Plan for Regulatory Science: Priorities Activities, Emerging Needs
  - Regulatory Science Collaboration
  - Scientific Excellence
- In each area, FDA will provide a Report to the Subcommittee on major activities and identify issues and specific questions for discussion and input
- We also plan to ask the Science Board to establish a separate subcommittee with specific expertise to evaluate IT

Area 1: FDA's Strategic Plan for Regulatory Science

- FDA will provide a report to the SC on its major activities in support of the Strategic Plan for Regulatory Science.
- We will request SC input re:
  - The strategic framework and priorities, including progress and gaps in addressing emerging technologies since 2007
  - Needs and opportunities in considering emerging science with a 10-20 year future horizon
  - How best to capture these needs in strategic planning /scientific activities to ensure FDA is prepared going forward
  - March-July 2013

Area 2: Regulatory Science Collaboration

- FDA will report to SC on collaborative activities and request feedback as well as suggestions for other collaborative opportunities and approaches
- August-November-2013

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Area 3. Scientific Excellence

- FDA will report on its activities in support of its scientific environment, culture, and training and professional development for FDA scientific staff
- We will seek SC input into:
  - Preparing our workforce for emerging scientific challenges and collaboration
  - Supporting efforts to train, recruit, and retain highly skilled scientific workforce and promote vibrant scientific culture
  - November 2013 – February 2014