Report to the Science Board

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Progress
Reflections
Challenges

Progress

I. Overarching Science Priorities

I. Overarching Science Priorities: Process

- Center Directors Identify Priorities
- Centers Develop Projects to Tackle each Priority
  - Hypothesis
  - Methods
  - Deliverables and timetable
  - Estimated budget
- Science Board Review

I. Overarching Science Priorities:

- Rapid, sensitive, high throughput detection of contaminants
- Biomarkers for safety and efficacy
- Adverse event detection and analysis
- Clinical trial design and analysis
- Personalized medicine and nutrition
- Microbial ecology and contamination mitigation strategies
- Manufacturing science

I: Overarching Science Priorities: Funding

- FDA internal projects – 3 years
- Centers of Excellence

Progress

II. Career Development and Training

II. Career Development and Training: Fellowship Program

- Vision for the Program:
  - Best and brightest, new science and scientists
  - Challenge convention
  - Exposes fellows to all FDA Centers
  - A program for preceptors, not just fellows

II. Career Development and Training: Fellowship Program

- Numbers too few for intended impact
  - Class of 2008 – 50 fellows
  - Class of 2009 – 50 accepting applications
- Steady state of 100 is only 14-15 per Center, 7 to 8 per Center entering FDA workforce if 50% remain at FDA

II. Career Development and Training: Fellowship Program: Course Work Year 1

Semester 1

- Core Introductory Courses:
  - FDA and Public Policy
  - FDA law
  - Negotiation and Influencing
  - Ethics and Decision Making
  - Beyond Our Borders
  - Conflict Management Skills
  - Briefing the Boss: Presenting to Senior Executives
  - Building Leadership Credibility
  - Decision Making for Leaders

II. Career Development and Training: Fellowship Program: Course Work Year 1

- Semester 2:
  - Statistical Methods and Applications - Maryland
  - Population Science/ Epidemiology - Maryland
  - Clinical Trial Design and Evaluation - Hopkins
- Summer Session:
  - MBA View of Drug Development: Duke/ Fuqua

II. Career Development and Training: Fellowship Program: Course Work Year 2

- **Semester 3-** core functions and science of the Centers:
  - Devices and Radiological Health
  - Foundations of Toxicology
  - Understanding Biologics and Their Evaluation
  - Understanding Drugs and Their Evaluation
  - Food and Nutrition Safety
  - Surveillance and Operations
  - Animal and Human Health: An Inseparable Link
- **Semester 4**:
  - Process Control Engineering and Chemistry
  - Risk Assessment / Risk Management
  - Case Studies in Translational and Regulatory Science
  - Elective

II. Career Development and Training: Fellowship Program: Research Projects

- A hypothesis driven project guided by a senior FDA preceptor:
  - Detailed research proposal
  - Oral presentation and final report
  - 60-70% time

II. Career Development and Training: FDA scientists

- Preceptors in the fellowship program
- Cross-Center sabbaticals
- Sabbaticals in academia
- Distinguished Speakers lecture series
  - February 25, 2009: Shaun Kennedy, U. of Minnesota
- "Science First" symposium series
  - April 2009: Nanotechnology
- Funds for workshop attendance
- Chief Scientist Challenge Grants
- Oncology professional development plan

Progress

III. Genomics Initiative

III: Genomics Initiative

- Genomics coordinator - Dr. Elizabeth Mansfield
  - Integrate “omics” into FDA regulatory decisions
  - Coordinate genomic research and data analysis
  - Develop enhanced informatics capability
  - Create an FDA-wide core facility to coordinate bioinformatics efforts

Progress

IV: Communicating FDA Regulatory Science

IV. Communicating FDA Regulatory Science

- Science Writers Symposium
  - November 2008
- FDA Journal of Regulatory Science
  - Peer reviewed e-journal to publish science and policy papers
  - Open to contributors outside FDA

Progress

V. Linking Science to the Agency's Informatics Initiative

V. FDA Informatics Initiative and the SB

- Review by Dr. Sangtae Kim in late 2008.
- Will ask Dr. McNeil to consider appointing a subcommittee of SB on Informatics to advise us as we engage in this major endeavor.

Progress

VI. Partnership with the Science Board

VI. Partnership with the Science Board: Agenda

- Rapid Detection - update
- Economically Motivated Adulteration - update
- Peer review of FDA's projects within scientific priority areas - plan
- Review of FDA Center Science - plan
- Biospecimens – plan
- BPA - update

VI. Partnership with the Science Board: BPA plan

- Opened assessment to external scrutiny and advice.
- Draft assessment: may change, regulatory decision could come at any time based on new information or further evaluation of existing data.
- Sequential effort to assess BPA in devices and other medical products.
- Four converging thrusts while we continue review of BPA exposure from food contact substances:
  - Joint efforts with Health Canada regarding industry efforts
  - Data collection, analysis based on SB comments
  - Animal toxicology – Partnership with NTP (NIH)
  - Human epidemiology – Partnership with NIH (NCI, NHLBI)

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