

Science and the FDA

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FDA science falls into non-traditional categories

- Developmental
- Applied
- Analytical

My view of science - and science at the FDA

- Freedom to ask questions
- Freedom to learn
- Freedom to communicate and interact
- Freedom to think

Building Science at the FDA

- Meetings with FDA Center leadership
- Science Report
- IOM report
- Statute

The job is to implement and
prioritize

Three Principles- First 100 days

Principle #1 The FDA cannot do it alone

- The FDA should partner more and smarter.
 - Enhance NIH/NCI/CDC/CMS/EPA/USDA partnerships around specific Center questions.
 - Pharma, Medical Device and Food Industries should be used to explore broad scientific issues of mutual interest.
 - Biotech should be better engaged to tackle specific FDA questions.
 - Academia should be engaged in regulatory science FDA-specific questions.
- The Critical Path Initiative

100 day Plan: #1-The FDA cannot do it alone

- **Constitute cross Center teams to identify top priority scientific questions that cross Centers and engage solutions from:**
 - **Gov't:** identify Gov't partners and develop interagency collaborations.
 - **Academia:** plan funding of targeted research at academic centers; initiate planning on the development FDA Regulatory Science Centers of Excellence.
 - **Pharma, Device and Food Industries:** identify working groups; co-develop analytic approaches through public-private partnerships
 - **Biotech:** outsource vexing technical scientific projects on FDA problems using contract mechanisms.
- **Facilitate recruitment of FDA scientists whose job description will be to integrate across Centers and engage external partners.**

Principle #2: FDA must maintain its core scientific expertise

- **In areas where science is critical to mission, substantive expertise must exist in-house.**

- **Skills of two types**
 - **Type I:** State-of-the-art scientific capability is necessary in-house.
 - **Type II:** State-of-the-art evaluative skills needed.

State-of-the-art scientific capability: examples

- **Genomic/large database access acquisition, evaluation interpretation: biostatistics, informatics, systems biology**
- **Rapid, risk-based assessment (biodefense, food, viral other pathogens)**
- **Clinical trial design/novel approaches**
- **Ecology/topology/aquaculture/environmental sciences**
- **Wireless devices/ Software devices**
- **Robotics**
- **Process Control Engineering/Chemistry**
- **Risk communication / Risk assessment science**

State-of-the-art scientific capability is necessary: more examples

- Nanotechnology
- Medical imaging
- Regenerative medicine
- Cell based products
- Combination products

100 Day Plan: #2 – FDA must maintain its core scientific expertise

- Build in-house teams in mission-critical science:
 - 1) write job descriptions with Centers
 - 2) begin hiring process into Centers
- Recruit scientists trained in critical cross center missions to lead, organize and integrate emerging science.
- Incorporate hiring plan into FY10 budget processes.
- Assess Center scientific priorities and coordinate with NCTR.
- Assure bioinformatics solutions serve the needs of FDA science.
- The scientists already here need a fair shake: conferences, CME, professional development.

Principle #3: The FDA scientific strategy must be preemptive

- Look forward:
 - There must be an overall scientific vision for the agency.
 - The FDA must develop an overall scientific process for vetting cross-cutting scientific issues.
 - Scientific hypotheses must be developed and tested.
 - Center-based science
 - NCTR support of science in Centers
- Look back:
 - Cochrane-like analytic capabilities must be developed to assess risk of additives in food, devices, drugs, etc.

100 Day Plan: The FDA scientific strategy must be preemptive

- Fellowship program
- Metaanalysis team
- Risk communications research team
- Press releases for scientific achievements at the FDA.
- FDA science education series for science writers, begin in June
- RFA for intramural cross-Center collaborative grants.
- Annual FDA science meeting
- Explore a Journal of Regulatory/Translational Science
- Preliminary budget recommendations for FY10

How the Board can Help

- Drill down in 8 areas of emerging science.
- Be involved as we execute our scientific vision and give us feedback.
- Participate in peer-review evaluation specific areas of science and science programs. Continue Center-wide reviews.
- Serve as sounding-board for new and controversial ideas and programs.
- Dialog with stakeholders.
- Identify new approaches /techniques developed in industry that may represent future regulatory challenges.
- Identify experiences for FDA scientists in academia (sabbaticals, practicums).
- Help with recruitment scientists to the FDA.

Final thoughts
