

Science Board Sub-Committee Review
National Center for Toxicological Research

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THANKS!

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- Jim Riviere
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- FDA Product Center Scientists
- Bill Slikker, Ph.D.
- NCTR Scientists
- Monica Spence

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CHARGE

- Review coordination between:
 - NCTR
 - FDA Product Center
- Prioritization of joint projects
- Utilization of resources

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PROCESS

- NCTR Senior Scientists
 - March 12, 2008
 - Jefferson, AR
- FDA Product Center Senior Scientists
 - April 3, 2008
 - Rockville, MD
- Weekly conference calls

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OBSERVATIONS

- NCTR
 - Central purpose science
 - Well run
 - Unique expertise
 - Committed
- FDA Centers
 - Regulates unique set of products
 - Extraordinary efforts
 - Less than adequate appropriations

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OBSERVATIONS

- NCTR and FDA
 - Expressed need to increase communications
 - Information Technology
 - Direct contact
 - Science Forum (on hold)
 - Science Symposium Series (smaller)
 - Joint projects originate from direct collaborations
 - A positive to be encouraged
 - Individual creativity
 - Serendipity

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OBSERVATIONS

- Possible negative effects on the prioritization process:
 - Special interest legislation
 - Legislative micromanagement
 - Advocacy organization pressure
 - Ear marks

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NCTR REPORTING STRUCTURE

- Office of Scientific & Medical Programs (OSMP)
 - NCTR one of three entities
 - OSMP reports directly to the Commissioner
 - Was headed by Janet Woodcock, MD
 - Now Director, Center for Drug Evaluation and Research

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NCTR REPORTING STRUCTURE

- Frank Torti, MD, MPH – Chief Scientist
 - Announced April 9, 2008
 - Food and Drug Administration Amendments Act of 2007
- Position recommendation made in "FDA Science and Mission at Risk" review

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December 2007 and May 2008 Findings

■ Finding 1

– NCTR location

- 2007 – Geography/distance is an issue
- 2008 – Not an issue. Communications could be accomplished by:
 - Improved IT
 - Increased travel budgets
 - Agency wide meetings

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December 2007 and May 2008 Findings

■ Finding 2

– Prioritization of FDA nominated compounds for National Toxicology Review (NTR)

- 2007 – NCTR submitted suggestions to the Sub-Committee for prioritization
- 2008 – A recurring theme in this review
 - Currently a complex process
 - Formal and informal systems
 - Appears to be working
 - Impression. A more centralized process would be more efficient

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December 2007 and May 2008 Findings

■ Finding 3

– Safety pharmacology studies at NCTR

- 2007 - Needs to be expanded
 - Priority setting process needed
- 2008 – Concur

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December 2007 and May 2008 Findings

■ Finding 4

- Priority-setting within NCTR must be coordinated with Product Centers
 - 2007 - Included in NCTR's 2007-2011 strategic plan
 - 2008 - FDA Product Centers very supportive of role that NCTR has played in their regulatory missions

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December 2007 and May 2008 Findings

■ Finding 5

- NCTR more support for Product Centers
 - 2007 - NCTR must be more supportive of the programmatic needs of Product Centers
 - 2008 - Product Centers are supportive of NCTR's role

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DECEMBER 2007 RECOMMENDATIONS

- Enhance the incorporation of safety pharmacology in the NCTR's mission
- Priority setting process similar to NIEHS/NTP should be applied across FDA
- NCTR applauded for collaborative research to support FDA needs
- NCTR can focus on integrated research
 - e.g. biomarkers for toxicity

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**MAY 2008
RECOMMENDATIONS**

- Positive evidence that NCTR provides a valuable and integrated resource for projects directly related to the regulatory functions of the FDA Product Centers.
- Physical distance is not a barrier to collaborations between NCTR and FDA Product Centers.

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**MAY 2008
RECOMMENDATIONS**

- Builds on and in agreement with "FDA Science and Mission at Risk"
 - Creation of modern IT and communication systems
 - Both have been damaged by minor budgetary needs
 - Science Forum
 - Projected related travel budgets

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**MAY 2008
RECOMMENDATIONS**

- Large worldwide corporations are using IT to:
 - Identify experts
 - Identify colleagues with shared interests
 - SourceCentral
- Some Product Centers developing databases of scientific projects
 - FDA wide database under development
 - FDA Research Database
- These efforts should be encouraged and adequately funded

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**MAY 2008
RECOMMENDATIONS**

- Science at the FDA needs an effective central structure
- Creation of an Executive Committee (EC)
 - Reports directly to the Commissioner
 - Includes Product Center leadership
 - Food safety and drug safety
 - Budget allocation authority
 - Provide overall direction

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CHIEF SCIENTIST AND EC

- Chief Scientist reports directly to the Commissioner
- Chair, or Co-Chair of the EC
 - Accountability for prioritization
- Politicalization has contributed to a loss in public confidence
 - Should not be a political appointee
 - Position should be filled from the ranks of senior FDA career scientists

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CHIEF SCIENTIST AND EC

- Deputy Director for Science created within each Product Center
 - Responsibility for organizing and managing science within Product Centers
 - Would represent Product Center on the EC

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CONCLUSIONS

- Mirror those of the "FDA Science and Mission at Risk"
- Need for strong centralized process for prioritization of science and allocation of scientific resources
- Adequate funding from Congress

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