

## **Draft Agenda**

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE  
Meeting # 27  
Hilton Hotel, Gaithersburg, MD**

### **Thursday, July 13, 2000**

- 8:30 a.m.** Call to Order  
Daniel Salomon, M.D., Chair
- 8:45** Conflict of Interest Statement  
Gail Dapolito, Executive Secretary
- 8:50** FDA Introduction  
Malcolm Moos Jr., M.D., Ph.D., Center for Biologics Evaluation and Research
- 8:55** Overview: Stem Cell Biology - Current Knowledge and Unanswered Questions  
John Gearhart, Ph.D., JHU School of Medicine
- 9:40** Isolation, Identification and Characterization of Bone Marrow-Derived Non-Hematopoietic Stem Cells Capable of Assuming Neuronal Phenotypes  
Catherine Verfaillie, M.D., Univ. Minnesota Stem Cell Institute
- 10:25** Break
- 10:35** Characterization of Lineage-Restricted, Self-Renewing Precursors from Neuroepithelial Stem Cells  
Mahendra Rao, M.D., Ph.D., University of Utah Medical School
- 11:20** Isolation, Identification, and Characterization of Adult Human Neural Progenitor Cells  
Steven Goldman, M.D., Ph.D., Cornell University Medical College
- 12:05** Lunch
- 1:05 p.m.** Anticipating Ethical Issues in Clinical Experiments Using Stem Cells for Neurological Disorders  
Jeremy Sugarman, M.D., M.P.H., M.A., Duke University Medical Center

## **BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE**

Meeting # 27

### **Thursday, July 13, 2000 - cont'd**

- 1:50 p.m.** Overview: Animal Models for Prognostic Safety Assessment of Neural Stem Cell Transplantation in Humans  
Fred Gage, Ph.D., The Salk Institute
- 2:35** Break
- 2:50** Animal Models for Evaluating Cell Therapy of Neurodegenerative Diseases  
John Trojanowski, M.D., Ph.D., University of Pennsylvania Center for Neurodegenerative Disease Research
- 3:35** Migration and Integration of Transplanted Stem Cells within the Recipient Nervous System  
Evan Snyder, M.D., Ph.D., Harvard Medical School
- 4:20** Break
- 4:35** Animal Models of Spinal Cord Injury as Paradigms for Stem Cell Therapy  
John McDonald, III, M.D., Ph.D., Washington University School of Medicine
- 5:20** Closing Remarks and Adjourn

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**Friday July 14, 2000**

<b>8:30 a.m.</b>	Call to Order Daniel Salomon, M.D., Chair
<b>8:40</b>	Presentation of Certificates Jay Siegel, M.D., CBER Kathryn Zoon, Ph.D., CBER
<b>9:00</b>	FDA Introduction Donald Fink, Ph.D., CBER
<b>9:10</b>	Open Public Hearing
<b>10:10</b>	Break
<b>10:20</b>	FDA Perspective - Questions Related to Product Development Malcolm Moos Jr., M.D., Ph.D., CBER
<b>10:25</b>	Committee Discussion of Questions - Product Development
<b>12:00</b>	Lunch
<b>1:00 p.m.</b>	FDA Perspective - Questions Related to Preclinical Models Mercedes Serabian, M.S., CBER
<b>1:05</b>	Committee Discussion of Questions - Preclinical Models
<b>3:00</b>	Closing Remarks and Adjourn

