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Food and Drug Administration
Center for Biologics Evaluation and Research
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
Meeting #37, March 18-19, 2004
Hilton Hotel, Silver Spring, Maryland

AGENDA

Thursday, March 18, 2004

- 8:30 a.m.** Call to Order/Introduction of Committee
 Mahendra Rao, M.D., Ph.D., Chair
- 8:40** Conflict of Interest Statement
 Gail Dapolito, Executive Secretary
- 8:45** FDA Opening Remarks
 Presentation of Certificates of Appreciation to Retiring Members
 Philip Noguchi, M.D., Director
 Office of Cellular, Tissue and Gene Therapies
 Center for Biologics Evaluation and Research, FDA

 Jesse Goodman, M.D., M.P.H., Director
 Center for Biologics Evaluation and Research (CBER), FDA
- 9:00** **Open Committee Discussion – Cellular Therapies for Cardiac Disease**
 FDA Perspective – Clinical Experience
 Dwaine Rieves, M.D., Chief
 Clinical Evaluation Branch
 Office of Cellular, Tissue and Gene Therapies, CBER
- 9:25** Guest Presentations
 Emerson Perin, M.D., F.A.C.C., Director
 New Cardiovascular Interventional Technology
 Texas Heart Institute
- 9:55** Q&A
- 10:05** Break
- 10:20 a.m.** Clinical Experience of Autologous Myoblast Transplantation
 Philippe Menasché, M.D., Professor
 Thoracic and Cardiovascular Surgery
 University of Paris
- 10:50 a.m.** Q&A

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Open Committee Discussion – Cellular Therapies for Cardiac Disease

- 11:00 a.m.** Steven Epstein, M.D., Executive Director
Cardiovascular Research Institute
Washington Hospital Center
- 11:30** Q&A
- 11:40** Lunch
- 12:40 p.m.** FDA Perspective – Preclinical Experience
Richard McFarland, Ph.D., M.D., Medical Officer
Pharmacology/Toxicology Branch
Office of Cellular, Tissue and Gene Therapies, CBER
- Guest Presentations
- 1:00** Myoblasts: The First Generation Cells for Cardiac Repair -
What Have We Learned?
Doris Taylor, Ph.D., Professor
Department of Physiology
University of Minnesota
- 1:30** Q&A
- 1:40** Silviu Itescu, M.B.B.S., Assistant Professor
Division of Surgical Science
Columbia University Medical Center
- 2:10** Q&A
- 2:20** From Mouse to Man: Is it a Logical Step for Cardiac Repair?
Doris Taylor, Ph.D.
University of Minnesota
- 2:50** Q&A
- 3:00** Break
- 3:15** Overview - Cardiac Catheters
Donald Nick Jensen, D.V.M., MSEE
Electrical Engineer
Office of Device Evaluation
Center for Devices and Radiological Health, FDA
- 3:35 p.m.** Q&A

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| | Open Committee Discussion – Cellular Therapies for Cardiac Disease |
| 3:45 p.m. | Preclinical Cardiac Catheter Models
Robert Lederman, M.D., Investigator
Cardiovascular Branch
National Heart, Lung and Blood Institute, NIH |
| 4:05 | Q&A |
| 4:15 | Open Public Hearing |
| 4:45 p.m. | Adjourn |