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

Executive Secretary

Gail Dapolito

Scientific Advisors & Consultants Staff Center for Biologics Evaluation and Research Food and Drug Administration (HFM-71) 1401 Rockville Pike Rockville, MD 20852-1448

Phone: (301) 827-1289 Fax: (301) 827-0294

E-mail: dapolito@cber.fda.gov

Committee Management Specialist

Rosanna L. Harvey

Scientific Advisors & Consultants Staff Center for Biologics Evaluation and Research Food and Drug Administration (HFM-71) 1401 Rockville Pike Rockville, MD 20852-1448

Phone: (301) 827-1297 Fax: (301) 827-0294 E-mail: harvey@cber.fda.gov

MEMBERS

CHAIR

Mahendra S. Rao, M.D., Ph.D. 03/31/03

Chief, Stem Cell Biology Section Laboratory of Neurosciences, 4B17 Gerontology Research Center National Institute on Aging National Institutes of Health 5600 Nathan Shock Drive Baltimore, MD 21224 **Jonathan S. Allan, D.V.M.** 03/31/06

Scientist

Department of Virology and Immunology Southwest Foundation for Biomedical Research 7620 N.W. Loop 410 at Military Drive San Antonio, TX 77030

Bruce R. Blazar, M.D.

03/31/05

Professor
Division of Pediatric Bone Marrow
Transplantation/Oncology
University of Minnesota
420 Delaware Street, SE, Box 109
Minneapolis, MN 55455

David M. Harlan, M.D.

03/31/06

Hea

Transplantation and Autoimmunity Branch National Institute of Diabetes and Digestive and Kidney Diseases, NIH 10 Center Drive, Building 10, Room 11S210 Bethesda, MD 20892

Katherine A. High, M.D.

03/31/05

William H. Bennett Professor of Pediatrics University of Pennsylvania Children's Hospital of Philadelphia 310 Abramson Research Center 3615 Civic Center Boulevard Philadelphia, PA 19104 Joanne Kurtzberg, M.D.

03/31/04

Professor of Pediatrics
Pediatric Bone Marrow and Stem Cell Program
Duke University Medical Center
Box 3350
2400 Pratt Street
Durham, NC 27710

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

MEMBERS (Cont'd)

Alison F. Lawton**

03/31/05

Senior Vice President Regulatory Affairs Genzyme Corporation One Kendall Square Cambridge, MA 02139

Richard C. Mulligan, Ph.D. 03/31/04

Mallinckrodt Professor of Genetics Harvard Medical School Children's Hospital Department of Molecular Medicine 320 Longwood Avenue Boston, MA 02115

Anastasios A. Tsiatis, Ph.D. 03/31/06

Professor Department of Statistics North Carolina State University Box 8203 2501 Founders Drive Raleigh, NC 27695 James J. Mulé, Ph.D. 03/31/07
Michael McGillicuddy Endowed Chair
in Melanoma Research and Treatment

H. Lee Moffitt Cancer Center and Research Institute 12902 Magnolia Drive, SRB-2

Tampa, FL 33612

Thomas H. Murray, Ph.D. 03/31/07

President
The Hastings Center
21 Malcolm Road
Garrison, NY 10524

Alice J. Wolfson, J.D.**

03/31/04

Wolfson and Bourhis 1050 Battery Street San Francisco, CA 94111

^{*} Consumer Representative

^{**} Industry Representative

^{*} Not Participating

FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting #37 March 18-19, 2004

CONSULTANTS

Jeffrey S. Borer, M.D.
Gladys and Roland Harriman Professor
of Cardiovascular Medicine
Division of Cardiovascular Pathophysiology
Joan and Sanford I. Weill Medical College
Cornell University
525 East 68th Street, Room F-467
New York, NY 10021

Susanna Cunningham, Ph.D.*
Professor
Department of Biobehavioral Nursing
School of Nursing
Box 357266
University of Washington
Seattle, WA 98195

Jeremy N. Ruskin, M.D.
Associate Professor of Medicine
Harvard Medical School
Cardiac Arrhythmia Service
Massachusetts General Hospital
55 Fruit Street
Boston, MA 02114

Michael D. Schneider, M.D.
M.D. Anderson Foundation Professor
Department of Medicine
The Center for Cardiovascular Development
Baylor College of Medicine
One Baylor Plaza, Room 506C
Houston, TX 77030

Michael Simons, M.D.
A.G. Huber Professor of Medicine
Department of Medicine
Dartmouth Medical School
Dartmouth Hitchcock Medical Center, Room 4A
1 Medical Center Drive
Lebanon, NH 03756

INDUSTRY REPRESENTATIVE

John F. Neylan, M.D.*
Vice-President
Clinical Research and Development
Transplantation, Immunology, Infectious
Disease and Cardiovascular
Wyeth Research
500 Arcola Road
Collegeville, PA 19426

GUEST HEALTH CANADA REPRESENTATIVE

Norman Viner, M.D.
Head, Clinical Trials Applications Unit
Clinical Evaluation Division
Biologics and Radiopharmaceuticals Evaluation Centre
Biologics and Genetic Therapies Directorate
Health Canada
Ottawa, Ontario, KIA 0L2
Canada

^{*}Consumer Representative *Non-Voting

FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting #37 March 18-19, 2004

GUEST SPEAKERS

Stephen E. Epstein, M.D. Executive Director Cardiovascular Research Institute Washington Hospital Center 110 Irving Street, N.W. Washington, D.C. 20010

Robert J. Lederman, M.D. Investigator, Cardiovascular Branch National Heart, Lung and Blood Institute National Institutes of Health Building 10, Room 2C713 10 Center Drive Bethesda, MD 20892

Emerson C. Perin, M.D., F.A.C.C. Director New Cardiovascular Interventional Technology Texas Heart Institute 6624 Fannin, Suite 2220 Houston, TX 77030 Silviu Itescu, M.D.
Associate Professor of Medicine and Surgery
Division of Surgical Science
Columbia University Medical Center
180 Fort Washington Avenue, Room 9-920
New York, NY 10032

Philippe Menasché, M.D.
Professor of Thoracic and Cardiovascular Surgery
University of Paris
Départment de Chirugie Cardio-vasculaire
Hôpital Européen George Pompidou
20, rue Leblanc
75015 Paris, France

Doris A. Taylor, Ph.D.
Medtronic Bakken Chair in Cardiovascular Repair
Department of Physiology
Biomedical Engineering Institute, 7-112 BSBE
University of Minnesota
310 Church Street, S.E.
Minneapolis, MN 55455

NIH PARTICIPANTS

Richard O. Cannon, M.D. Clinical Director National Heart, Lung and Blood Institute National Institutes of Health Building 10, Room 7B15 10 Center Drive Bethesda, MD 20892 Stephen M. Rose, Ph.D.
Deputy Director
Recombinant DNA Program
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 762
Bethesda, MD 20892

FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting #37 March 18-19, 2004

FDA PARTICIPANTS

Jesse L. Goodman, M.D., M.P.H. Director Center for Biologics Evaluation and Research Food and Drug Administration 1401 Rockville Pike, HFM 1 Rockville, MD 20852

Cynthia Rask, M.D.
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM 755
Rockville, MD 20852

Dwaine Rieves, M.D.
Chief, Clinical Evaluation Branch
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM 755
Rockville, MD 20852

Stephen Grant, M.D.
Medical Officer, Clinical Evaluation Branch
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM 755
Rockville, MD 20852

Philip Noguchi, M.D.
Acting Director
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research. FDA
1041 Rockville Pike, HFM 710
Rockville, MD 20852

Raj Puri, M.D., Ph.D.
Acting Director
Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM 735
Rockville, MD 20852

Kimberly Benton, Ph.D.
Acting Chief, Cell Therapy Branch
Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM 720
Rockville, MD 20852

Ellen Areman, M.S., SBB(ASCP)
Biologist, Cell Therapy Branch
Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM 710
Rockville, MD 20852

FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE Meeting #37 March 18-19, 2004

FDA PARTICIPANTS (Cont'd)

Mercedes Serabian, M.S., D.A.B.T.
Chief
Pharmacology/Toxicology Branch
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM 760
Rockville, MD 20852

Elias Mallis, B.S.E.E.
Chief, Clinical Electrophysiology and
Monitoring Branch
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard, HFZ 450
Gaithersburg, MD 20877

Richard McFarland, Ph.D., M.D.
Medical Officer
Pharmacology/Toxicology Branch
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM 760
Rockville, MD 20852

Donald Nick Jensen, D.V.M., M.S.E.E.
Electrical Engineer, Clinical Electrophysiology and Monitoring Branch
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard, HFZ 450
Gaithersburg, MD 20877

BRMAC #37 FDA Working Group Ellen Areman, M.S., SBB(ASCP)

Kimberly Benton, Ph.D.
Stephen Grant, M.D.
Donald Nick Jensen, D.V.M., M.S.E.E.
Ellen Lazarus, M.D.
Elias Mallis, B.S.E.E.
Richard McFarland, Ph.D., M.D.
Philip Noguchi, M.D.
Pai Puri, M.D., Ph.D.

Raj Puri, M.D., Ph.D. Cynthia Rask, M.D.

Dwaine Rieves, M.D.

Mercedes Serabian, M.S., D.A.B.T.

Stephanie Simek, Ph.D.

Joyce Frey-Vasconcells, Ph.D.