

**Food and Drug Administration
Center for Biologics Evaluation and Research
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
MEETING #34, FEBRUARY 27, 2003
Holiday Inn, 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

Daniel R. Salomon, M.D. 03/31/03
Associate Professor
Department of Molecular and Experimental Medicine
The Scripps Research Institute
10550 N. Torrey Pines Road, MEM 55
La Jolla, CA 92037

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
Head
Transplantation and Autoimmunity Branch
National Institute of Diabetes and Digestive
and Kidney Disease, 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

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
Meeting #34, February 27, 2003

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

Mahendra S. Rao, M.D., Ph.D. 03/31/05
Chief, Stem Cell Biology Section
Laboratory of Neurosciences, 4B17
Gerontology Research Center
National Institute on Aging, NIH
5600 Nathan Shock Dr.
Baltimore, MD 21224

Anastasios A. Tsiatis, Ph.D. 03/31/06
Professor
Department of Statistics
North Carolina State University
Box 8203
2501 Founders Drive
Raleigh, NC 27695

Alice J. Wolfson, J.D. ** 03/31/04
Bourhis, Wolfson and Schlichtmann
1050 Battery Street
San Francisco, CA 94111

* - Industry Representative
** - Consumer Representative
+ - Not Attending

TEMPORARY VOTING MEMBERS

Mary M. Horowitz, M.D.
Professor of Medicine
International Bone Marrow Transplant Registry
Autologous Blood and Marrow Transplant
Registry
Health Policy Institute
Medical College of Wisconsin
8701 Watertown Plank Road, HRC Suite 2500
Milwaukee, WI 53226

Harvey G. Klein, M.D.
Chief
Department of Transfusion Medicine
National Institutes of Health
Warren G. Magnuson Clinical Center
Building 10, Room 1C711
10 Center Drive
Bethesda, MD 20892

Jeanne V. Linden, M.D.
Director
Blood and Tissue Resources
New York State Department of Health
Wadsworth Center
Empire State Plaza
Albany, NY 12201

David F. Stroncek, M.D.
Chief, Laboratory Service Section
Department of Transfusion Medicine
National Institutes of Health
Warren G. Magnuson Clinical Center
Building 10, Room 1C733
10 Center Drive
Bethesda, MD 20892

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
Meeting #34, February 27, 2003

NIH REPRESENTATIVE

Liana Harvath, Ph.D.
Director
Blood Resources Program
Division of Blood Diseases and Resources
National Heart, Lung and Blood Institute
Rockledge II, Room 10170
6701 Rockledge Drive
Bethesda, MD 20892

GUEST SPEAKERS

Nelson J. Chao, M.D., M.B.A.
Professor
Department of Medicine
Duke University Medical Center
Box 3961
Durham, NC 27710

Pablo Rubinstein, M.D.
Director
National Cord Blood Program
New York Blood Center
310 E. 67th Street
New York, NY 10021

John E. Wagner, M.D.
Associate Professor of Pediatrics
University of Minnesota School of Medicine
660C Cancer Center Research Building
Box 366 UMHC
420 Delaware Street, S.E.
Minneapolis, MN 55455

FDA PARTICIPANTS

Philip D. Noguchi, M.D.
Acting Director
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM-515
Rockville, MD 20852

Ruth Solomon, M.D.
Acting Director
Division of Human Tissues, OCTGT
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, HFM-770
Rockville, MD 20852

Ellen F. Lazarus, M.D.
Reviewing Medical Officer
Division of Clinical Evaluation and
Pharmacology and Toxicology
Office of Cellular, Tissue and Gene Therapies
Food and Drug Administration
1401 Rockville Pike, HFM-770
Rockville, MD 20852

Stephen D. Litwin, M.D.
Medical Officer
Division of Clinical Evaluation and
Pharmacology and Toxicology
Office of Cellular, Tissue and Gene Therapies
Food and Drug Administration
1401 Rockville Pike, HFM-755
Rockville, MD 20852

BRMAC #34 CBER Working Group

February 27, 2003

Dr. Philip Noguchi

Dr. Joyce Frey-Vasconcells

Dr. Ruth Solomon

Dr. Ellen Lazarus

Dr. Steve Litwin

Dr. Cynthia Rask

Dr. Martha Wells

Dr. Ellen Areman

Dr. Jean Wang