



ANNUAL REPORT
OF THE
CELLULAR, TISSUE AND GENE THERAPIES ADVISORY COMMITTEE
(formerly the Biological Response Modifiers Advisory Committee)

For the period

October 1, 2004 through September 30, 2005

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Foods and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met four times during the reporting period. Meetings were held in Bethesda, Maryland and Rockville, Maryland.

The dates of those meetings were March 3-4, 2005, May 20, 2005, July 29, 2005, and September 29, 2005.

The meetings on May 20, 2005, July 29, 2005, and September 29, 2005 included a closed session to permit discussion of matters of a personal nature and trade secret and/or confidential information.

ACCOMPLISHMENTS

May 20, 2005 in Rockville, Maryland via teleconference. The Committee reviewed and discussed the following topics: the Clinical Proteomics Program and the research programs in the Division of Therapeutic Proteins. The Committee held a closed session to discuss and make recommendations on personnel and program actions for the Laboratory of Chemistry and the Laboratory of Immunology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

July 29, 2005 in Bethesda, Maryland via teleconference. The topics included an Open Public Hearing on the Division of Therapeutic Proteins. The Committee held a closed session to discuss and make recommendations on personnel and program actions for the Laboratory of Chemistry and the Laboratory of Immunology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

September 29, 2005 Subcommittee meeting. The Subcommittee discussed and made recommendations on the research program of the Office of Cellular, Tissue and Gene Therapies. The discussions related to components of the Strategic Plan of 2004 and FDA's Critical Path to New Medical Products. The Committee held a closed session to permit discussion of personnel and program actions for intramural programs in the Office of Cellular, Tissue and Gene Therapies. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6) and the review of trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The recommendations will be discussed at a future meeting of the Cellular, Tissue and Gene Therapies Advisory Committee.

Detailed information related to these meetings is available in the annual report.

October 26, 2005
Date

Gail Dapolito
Gail Dapolito
Executive Secretary

**Cellular, Tissue and Gene Therapies Advisory Committee
(formerly the Biological Response Modifiers Advisory Committee)**

Committee Roster

Chair

Mahendra S. Rao, M.D., Ph.D.

Expertise: Cellular Biology
Term: 05-22-2001 - 03-31-2006
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, Maryland 21224

Jonathan S. Allan, D.V.M.

Expertise: Veterinary Medicine
Term: 09-30-2002 - 03-31-2006
Scientist
Department of Molecular and Experimental
Medicine
Department of Virology and Immunology
Southwest Foundation for Biomedical
Research
7620 N.W. Loop 410 at Military Drive
San Antonio, Texas 77030

Michèle P. Calos, Ph.D.

Expertise: Biochemistry/Molecular Biology
Term: 09-13-2004 - 03-31-2008
Associate Professor of Genetics
Department of Genetics, Rm. 334
Stanford University School of Medicine
300 Pasteur Drive
Stanford, California 94305-5120

Jeffrey S. Chamberlain, Ph.D.

Expertise: Genetics/Gene Therapy
Term: 09-29-2005 – 03-31-2009
Professor
Departments Neurology, Medicine and
Biochemistry
Health Sciences Center
University of Washington School of Medicine
1959 N.E. Pacific Street
Seattle, Washington 98195-7720

Executive Secretary

Gail Dapolito

Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike (HFM-71)
Rockville, Maryland 20852-1448
E-mail: dapolito@cber.fda.gov
Phone: 301-827-0314
Facsimile: 301-827-0294

James J. Mule, Ph.D.

Expertise: Tumor Immunology /
Immunotherapy
Term: 01-05-2004 - 03-31-2007
Associate Center Director
Translation Science and Technology
Development
Michael McGillicuddy Endowed Chair
Melanoma Research and Treatment
H. Lee Moffitt Cancer Center and
Research Institute
12902 Magnolia Drive, SRB-2
Tampa, Florida 33612

Sharon F. Terry, MS*

Expertise: Genetics/Consumer
Representative
Term: 01-23-2005 - 03-31-2008
President and CEO
Genetic Alliance Organization
Suite 404
4301 Connecticut Avenue, NW
Washington, DC 20008-2369

William W. Tomford, Ph.D.

Expertise: Orthopedic Surgery
Term: 09-13-2004 - 03-31-2008
Professor of Orthopedic Surgery
Massachusetts General Hospital
55 Fruit Street
Boston, Massachusetts 02114

Kurt C. Gunter, M.D.**
Expertise: Industry Representative
Term: 09-29-2005 – 03-31-2009
Vice President, Clinical and Medical
Affairs/Government Relations
ZymeQuest, Inc.
100 Cummings Center
Suite 436H
Beverly, Massachusetts 01915-6122

David M. Harlan, M.D.
Expertise: Transplantation, Autoimmunity
Term: 09-30-2002 - 03-31-2006
Captain, U.S. Public Health Service and
Chief, Islet and Autoimmunity Branch
National Institute of Diabetes and Digestive
and Kidney Disease, NIH, DHHS
10 Center Drive, Building 10, Room 8N307
Bethesda, Maryland 20892

Anastasios A. Tsiatis, Ph.D.
Expertise: Biostatistics
Term: 09-30-2002 - 03-31-2006
Professor
Department of Statistics
North Carolina State University, Box
8203
2501 Founders Drive
Raleigh, North Carolina 27696

Walter John Urba, M.D., Ph.D.
Expertise: Hematology/Oncology
Term: 09-29-2005 – 03-31-2009
Medical Director
Robert W. Franz Cancer Research Center
Earle A. Chiles Research Institute
Providence Portland Medical Center
4805 N.E. Glisan St., 5F-40
Portland, Oregon 97213

*Consumer Representative

**Industry Representative