



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ANNUAL REPORT
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE

for the period

October 1, 2003 through September 30, 2004

FUNCTION

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The Panels engage in a number of activities to fulfill the functions the Federal Food, Drug and Cosmetic Act envisions for device advisory Panels. With the exception of the Medical Devices Dispute Resolution Panel, each Panel, according to its specialty area, advises the Commissioner of Food and Drugs regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each Panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug Panel. The functions of the dental drug Panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory Panel proceedings or Agency decisions or actions.

MEETINGS

The Medical Devices Advisory Committee held 21 meetings during the reporting period in Gaithersburg, Maryland.

Below are the dates of all device panel meetings during FY 2004 (10/1/03 to 9/30/04) and UNDERLINED dates represent meetings that had closed sessions:

10/02/03	Circulatory System Devices Panel
10/03/03	Ophthalmic Devices Panel
10/14-15/03	General and Plastic Surgery Devices Panel
11/20/03	Circulatory System Devices Panel
11/21/03	General and Plastic Surgery Devices Panel
<u>12/11/03</u>	Orthopaedic and Rehabilitation Devices Panel
<u>02/03/04</u>	Radiological Devices Panel
<u>02/5-6/04</u>	Ophthalmic Devices Panel
02/23/04	Neurological Devices Panel
03/05/04	Ophthalmic Devices Panel
03/17-18/04	Circulatory System Devices Panel
03/25/04	General and Plastic Surgery Devices Panel
04/21/04	Circulatory System Devices Panel
06/2-3/04	Orthopaedic and Rehabilitation Devices Panel
06/03/04	Obstetrics and Gynecology Devices Panel
06/08/04	Circulatory System Devices Panel
06/15/04	Neurological Devices Panel
<u>07/13/04</u>	Dental Product Panel
07/28-29/04	Circulatory System Devices Panel
08/31/04	Orthopaedic and Rehabilitation Devices Panel
09/21/04	Circulatory System Devices Panel

DENTAL PRODUCTS PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Panel met once during the reporting period in Gaithersburg, Maryland.

The date of the meeting was July 13, 2004.

The meeting on July 13, 2004, included a closed session to permit a discussion of trade secret or confidential commercial information.

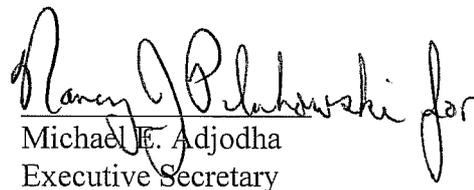
ACCOMPLISHMENTS

In the open session, the Panel recommended an approval with conditions on a PMA from BioMimetic Pharmaceutical, Inc. for the GEM21S™. The GEM 21S™ is a combination product consisting of a beta-tricalcium phosphate bone void filler combined with Becaplermin, a wound-healing drug, to treat osseous defects resulting from periodontal disease, cystectomy, apicoectomy, deficient alveolar ridges, and tooth extraction. The Panel's conditions included: (1) there should be no labeling claims of superiority over other devices considering the primary endpoint, i.e. clinical attachment level; and (2) labeling should be restricted to use only for periodontal related defects.

Closed Committee Deliberations: On July 13, 2004, the meeting was closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future agency issues (5 U.S.C.552b(c)(4)).

September 30, 2004

Date


Nancy J. Pelukowski for
Michael E. Adjodha
Executive Secretary

Dental Products Panel Roster

Chairperson

Jon B. Suzuki, D.D.S., Ph.D.

Expertise: Periodontics

Term: 3/22/04 - 10/31/05

Associate Dean for Graduate Education,
Research and Intl. Affairs

Dir. of Graduate Periodontics and Professor of
Periodontics

Temple University School of Dentistry

Office of the Dean

3223 N. Broad Street

Philadelphia, PA 19140

Leslie B. Heffez, DMD

Expertise: Oral/Maxillofacial Surgery

Term: 8/29/00 - 10/31/03

Professor and Head,

Oral/Maxillofacial Surgery

College of Dentistry, University of
Illinois at Chicago

801 South Paulina Street MC 835

Chicago, IL 60612

Executive Secretary

Michael E. Adjodha

Center for Devices and Radiological Health

Office of Device Evaluation/DAGID

9200 Corporate Blvd. HFZ-480

Rockville, MD 20850

(301) 827-5283 x 123

(301) 480-3002

Salomon Amar, D.D.S., Ph.D.

Expertise: Periodontics; Dental Sciences,
Clinical

Term: 3/22/04 - 10/31/07

Professor

Dept. of Periodontology and Oral Biology

Boston University

700 Albany Street, W201E

Boston, MA 02118

William J. O'Brien, M.S., Ph.D.

Expertise: Material Sciences

Term: 3/22/04 - 10/31/07

Professor of Dentistry

Dept. of Biologic and Materials Science

Univ. of Michigan School of Dentistry

1011 N. University, Room 2203

Ann Arbor, MI 48103

David L. Cochran, D.D.S., Ph.D.

Expertise: Periodontics

Term: 2/19/02 - 10/31/05

Professor and Chairman

Dept. of Periodontics MSC 7894

The Univ. of Texas Hlth. Sci. Ctr. at San
Antonio

7703 Floyd Curl Drive, Rm. 3-55IU

San Antonio, TX 78284-7894

Elizabeth D. Rekow, D.D.S., Ph.D.

Expertise: Dental Sciences

Term: 8/29/00 - 10/31/03

Dir. Translational Research, Prof. Orthodontics

NYU College of Dentistry

345 East 24th Street

Room 1003S

New York, NY 10010-409

Raymond J. Fonseca, M.D.

Expertise: Oral Surgery

Term: 8/29/00 - 10/31/03

Dean

School of Dental Medicine

University of Pennsylvania

4001 Spruce Street

Philadelphia, PA 19104-6003

****Daniel R. Schechter, Esq.**

Expertise: Business Law

Term: 1/13/02 - 10/31/05

General Counsel

Parkell, Inc.

155 Schmitt Boulevard

Farmingdale, NY 11735

Domenick T. Zero, D.D.S., M.S.

Expertise: Cariology; Dental Sciences, Clinical

Term: 3/22/04 - 10/31/07

Professor and Chairman

Preventive and Community Dentistry

Indiana Univ. School of Dentistry

415 Lansing Street

Indianapolis, IN 46202-2876

***Elizabeth S. Howe**

Expertise: Social Sciences
Term: 12/16/01 - 10/31/05
Outreach Coordinator
National Foundation for Ectodermal
Dysplasias
P. O. Box 2069
Auburn, WA 98071

John R. Zuniga, Ph.D., D.M.D.

Expertise: Oral Surgery; Neurosciences
Term: 3/22/04 - 10/31/06
Professor and Graduate Program Director
Dept. of Oral and Maxillofacial Surgery
Univ. of North Carolina School of Dentistry
115 Brauer Hall, CB#7450
Chapel Hill, NC 27599-7450

Man Wai Ng, D.D.S., M.P.H.

Expertise: Pediatric Dentistry; Dental Health,
Clinical
Term: 3/22/04 - 10/31/06
Chief, Department of Dentistry
Department of Dentistry
Children's Hospital Boston
300 Longwood Ave.
Boston, MA 02115

**Industry Representative

*Consumer Representative

OPHTHALMIC DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Panel met three times during the reporting period in Gaithersburg, Maryland.

The dates of those meetings were October 3, 2003, February 5-6, 2004, and March 5, 2004.

The meeting on February 5-6, 2004, included a closed session to permit a discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the October 3, 2003 meeting:

In the open session, a PMA supplement for the STAAR Myopic Implantable Contact Lens (ICL™) was recommended for approval with conditions. The device, a phakic intraocular lens, is indicated for the correction of moderate to high myopia with placement in the posterior chamber of the phakic eye. The Panel's conditions included changes in the indications for use, additions to both patient and physician labeling and consideration of post-market studies.

At the February 5-6, 2004 meeting:

In the open session, during the first day, a PMA for the ARTISAN™ Myopia Phakic Intraocular lens was recommended for approval with conditions. The device is indicated for the reduction or elimination of myopia in adults. The conditions included:

- Agency should determine the age and minimum corneal endothelial cell count allowable for implantation of the lens.
- The sponsor should reanalyze the existing data for pigment dispersion and elevated intraocular pressure in the minority subset of the cohort.
- Perform a 2-3 year post-market study to further evaluate the incidence of retinal detachments, lens explants, and cataract formation.
- Strengthen the physician and patient labeling with various recommendations including clarification or elimination of confusing terms, and additional warnings and precautions.

Agency Action: On September 10, 2004, FDA issued an approval order for the device.

On the second day, a PMA for the Viewpoint™ Conductive Keratoplasty (CK) System was recommended for approval with conditions. This radiofrequency electro-surgical corneal shaping device is indicated for the temporary spherical treatment in the non-dominant eye of presbyopic emmetropes or presbyopic hyperopes. One condition was slightly restricting the indications statement to reflect an intended range of refractive correction to 1.00 to 2.25 diopters of effect.

Ophthalmic Devices Panel (*continued*)

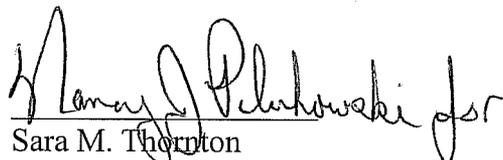
The other condition strengthened the physician and patient labeling by adding information: (a) safety and effectiveness of retreatments have not been determined; (b) nystagmus should be a contraindication; (c) a table that defines the frequency of induced astigmatism and the effect on near and distance vision; and (d) a graph of the total effect of regression over time to focus attention on the temporary nature of the procedure's vision improvement.

Closed Committee Deliberations: On February 6, 2004, the meeting was closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information relevant to pending and future device submissions for vitreoretinal, surgical and diagnostic devices, intraocular and corneal implants, and contact lenses. This portion of the meeting was closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

At the March 5, 2004 meeting:

The Panel discussed issues related to the appropriate clinical trial design for the evaluation of multifocal or accommodative intraocular lenses (IOLs) in a cohort of subjects who have undergone clear lens extraction to correct presbyopia. Clear lens extraction is an intraocular surgical procedure in which the non-cataractous crystalline lens is removed and replaced with a multifocal or accommodative lens for refractive correction. There was no vote taken nor consensus requested of the Panel. The purpose of the meeting was to assist FDA in working with industry to design clinical trial protocols that would establish the reasonable safety and effectiveness of clear lens extraction with implantation of a multifocal or accommodative IOL.

September 30, 2004
Date


Sara M. Thornton
Executive Secretary

Ophthalmic Devices Panel Roster

Chairperson

Jayne S. Weiss, M.D.

Expertise: Ophthalmological Surgery
Term: 3/25/02 - 10/31/04
Prof. Ophthalmology and Pathology
Director of Ophthalmic Pathology
Kresge Eye Institute, Wayne State Univ.
4717 St. Antoine Blvd.
Detroit, MI 48201

Arthur Bradley, Ph.D.

Expertise: Visual Physiology
Term: 11/1/00 - 10/31/04
Professor of Visual Science
Indiana Univ. School of Optometry
Dept. of Visual Sciences
800 East Atwater Ave.
Bloomington, IN 47405-

Anne L. Coleman, M.D., Ph.D.

Expertise: Ophthalmological Surgery
Term: 3/25/02 - 10/31/05
Professor of Ophthalmology
Department of Ophthalmology
Jules Stein Eye Institute, UCLA Sch of
Medicine
100 Stein Plaza
Los Angeles, CA 90095-7004

Michael R. Grimmatt, M.D.

Expertise: Ophthalmology
Term: 11/1/00 - 10/31/04
Grimmett Eye Care, PLLC.
3385 Burns Road
Suite 209
Palm Beach Gardens, FL 33410

Allen C. Ho, M.D.

Expertise: Ophthalmology
Term: 3/25/02 - 10/31/05
Associate Surgeon
Retinovitreal Associates
910 East Willow Grove Avenue
Wyndmoor, PA 19038

Executive Secretary

Sara Thornton

Center for Devices and Radiological Health
Office of Device Evaluation/DOED
9200 Corporate Blvd. HFZ-460
Rockville, MD 20850
(301) 594-2053 x127
(301) 827-4601

Alice Y. Matoba, M.D.

Expertise: Ophthalmology
Term: 2/27/00 - 10/31/03
Associate Prof. of Ophthalmology
Baylor College of Medicine, Cullen
Eye Institute
6565 Fannin, NC-205
Houston, Texas 77030

William D. Mathers, M.D.

Expertise: Ophthalmology
Term: 11/1/03 - 10/31/07
Professor of Ophthalmology
Department of Ophthalmology
Oregon Health Sciences University
3375 SW Terwilliger Blvd.
Portland, OR 97201-4197

****Ronald E. McCarley**

Term: 11/18/01 - 10/31/05
President & CEO
Ophtec, USA, Inc.
6421 Congress Avenue Suite 112
Boca Raton, FL 33487

Timothy T. McMahon, O.D., F.A.O.

Expertise: Optometry
Term: 3/25/02 - 10/31/05
Professor of Ophthalmology
Dept. of Ophthalmology & Visual Sciences
University of Illinois at Chicago
1855 W. Taylor Street, Suite 3.164
Chicago, IL 60612

*** Glenda V. Such, M.Ed.**

Expertise: Educational Psychology
Term: 11/18/01 - 10/31/05
Director of Computer Training Programs
Career Services Dept.
Lighthouse International
111 E. 59th Street
New York, NY 10022

*Consumer Representative

**Industry Representative

ORTHOPAEDIC and REHABILITATION DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Panel met three times during the reporting period in Gaithersburg, Maryland.

The dates of the meetings were December 11, 2003, June 2-3, 2004, and August 31, 2004

The meeting on December 11, 2003, included a closed session to permit a discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the December 11, 2003 meeting:

The Panel considered an FDA-initiated reclassification of the intervertebral body fusion cage device from class III to class II. The device is intended for spinal fusion procedures in skeletally mature adults with degenerative disc disease (DDD) at one or two levels from C2-C7 and L2-S1 using autogenous bone graft. The device does not include combination products, such as the intervertebral body fusion device using morphogenic proteins and scaffolds. The Panel recommended that FDA reclassify the device into class II using three special controls to reasonably assure the safety and effectiveness of the device: (1) a guidance document that may include clinical data for designs and materials beyond those currently approved; (2) device tracking for all implants not just cages for a limited period of time; and (3) testing guidelines, which include fracture toughness, potential response to wear particulates, and device retrieval analysis for a limited number of explanted devices.

Agency Action: FDA is drafting a reclassification rulemaking for this device.

Closed Committee Deliberations: On December 11, 2003, the meeting was closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

At the June 2-3, 2004 meeting:

On June 2, 2004, the open session, the Panel recommended conditional approval for Depuy Spine, Inc.'s PMA for Charité Artificial Disc. The device is intended for spinal arthroplasty in skeletally mature patients with degenerative disc disease at one level from L4-S1. The conditions were:

- A post-market study of all patients enrolled in the investigational device exemption (IDE) (including continued access patients) should be followed until the last-enrolled continued access subject reaches the 2 year time point, and the data will be provided the FDA.

Orthopaedic and Rehabilitation Devices Panel (continued)

- All patients treated with the device should be provided with documentation describing the specific components of their implant, including associated lot numbers, as well as a telephone number to be used for the reporting of any adverse events.
- A post-market *in-vitro* study to further assess wear debris.
- FDA should consider required surgeon training.
- FDA and the sponsor should discuss certain additional conditions and reach a mutually agreeable course of action. This discussion will consider whether these conditions should be addressed pre- or post-market.

On June 3, 2004, the Panel made recommendations to FDA regarding the Orthopedic Surgical Manufacturers Association's petition to reclassify the total mobile bearing knee (MBK) and unicompartamental MBK intended to replace the total knee or part of the knee joint, respectively, from class III into class II. The Panel recommended that FDA reclassify the total MBKs into class II. They suggested five special controls to reasonably assure the safety and effectiveness of the devices: (1) a special controls guidance document; (2) testing guidelines; (3) potential use of clinical data; (4) device specific training and labeling (to be negotiated with sponsors); and (5) patient identification cards (to include patient, surgeon, hospital, and implant information). They also recommended that FDA reclassify the unicompartamental MBK into class II. The Panel recommended the same special controls as identified for the total MBK, with a stronger emphasis placed on the use of clinical data. In addition, the Panel also urged post-market surveillance to track such adverse events as osteolysis, bearing dislocations, polyethylene failures, and revisions.

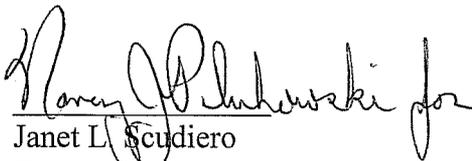
Additionally, the Panel made recommendations to the FDA regarding Orthopedic Surgeon Manufacturers Association's (OSMA) guidance document submission entitled Clinical Trial Design for Hip Replacement Systems. The main focus of the submission was a proposed clinical study design for evaluating the safety and effectiveness of total hip joint replacement systems. The design includes a composite endpoint consisting of three objective performance criteria as a control for patient success with a benchmark for overall study success and a 4% delta for noninferiority.

At the August 31, 2004 meeting:

In the open session, the Panel deliberated on St. Francis Medical Technologies, Inc.'s PMA for the X Stop Interspinous Process Distraction System. The device is indicated for patients aged 50 years or older suffering from neurogenic intermittent claudication secondary to mild or moderate lumbar spinal stenosis, who have undergone a regimen of nonoperative treatment and experience relief in flexion from their symptoms of leg/buttock/groin pain, with and without back pain. After deliberations, the Panel recommended that the PMA be found not approvable. The Panel cited several concerns regarding the data; they discussed several options for the sponsor to put the PMA in an approvable form.

September 30, 2004

Date


Janet L. Scudiero
Executive Secretary

Orthopaedic and Rehabilitation Devices Panel Roster

Chairperson

Michael J. Yaszemski, M.D., Ph.D.

Expertise: Orthopedic Surgery
Term: 11/13/02 - 8/31/05
Senior Associate Consultant and Associate Professor
Dept. of Orthopedic Surgery
Mayo Clinic and Graduate School of Medicine
200 1st Street SW
Rochester, MN 55905

Maureen A. Finnegan, M.D.

Expertise: Orthopedic Surgery
Term: 10/11/00 - 8/31/04
Associate Professor
Dept. of Orthopaedic Surgery
Univ. of Texas Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-8883

Richard J. Friedman, M.D.

Expertise: Orthopedic Surgery
Term: 11/13/02 - 8/31/06
Clinical Professor of Orthopaedic Surgery
Medical University of South Carolina
2270 Ashley Crossing Dr. Suite 110
Charleston, SC 29414

Choll W. Kim, M.D., Ph.D.

Expertise: Spinal Surgery; Biomaterials
Term: 9/1/04 - 8/31/08
Assistant Professor--Spine Surgery
Dept. of Orthopaedic Surgery
Univ. of California, San Diego
3350 La Jolla Village Dr., MC#112D
San Diego, CA 92161

John S. Kirkpatrick, M.D.

Expertise: Orthopedic Implants
Term: 11/13/02 - 8/31/06
Associate Professor
Dept. of Surgery, Div. of Orthopaedic Surgery
Univ. of Alabama School of Medicine Faculty
510 20th St South FOT-Suite 940
Birmingham, AL 35294-3295

Executive Secretary

Janet Scudiero

Center for Devices and Radiological Health
Office of Device Evaluation/DGRND
9200 Corporate Blvd. HFZ-410
Rockville, MD 20850
(301) 594-1184 X 176
(301) 594-2358

Kinley Larntz, Ph.D.

Expertise: Biostatistics
Term: 11/13/02 - 8/31/05
Professor Emeritus
Dept. of Applied Statistics
University of Minnesota
6339 East Greenway, #102-172
Scottsdale, AZ 85254-6517

Stephen Li, Ph.D.

Expertise: Biomaterials; Materials Science
Term: 10/11/00 - 8/31/04
President
Medical Device Testing and Innovations
1469 Tallevast Road
Sarasota, FL 34243

Sanjiv H. Naidu, M.D., Ph.D.

Expertise: Orthopedic Surgery
Term: 11/13/02 - 8/31/06
Associate Professor of Orthopaedic Surgery
Dept. of Orthopaedics and Rehabilitation
Pennsylvania State Univ., Hershey Medical Ctr
500 University Dr.
Hershey, PA 17033

Sally A. Rudicel, M.D.

Expertise: Orthopedics Surgery
Term: 9/1/04 - 8/31/08
Associate Professor
Dept. of Orthopaedics
Tufts Univ., New England Medical Center
750 Washington Street
Box 306
Boston, MA 02111

****Sally Maher, ESQ**

Expertise: Bacteriology
Term: 12/31/00 - 8/31/04
Senior Director, Regulatory Affairs
Clinical Research
Smith & Nephew Endoscopy
150 Minuteman Road
Andover, MA 01810

** Industry Representative

RADIOLOGICAL DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Panel met once during the reporting period in Gaithersburg, Maryland.

The date of the meeting was February 3, 2004.

The meeting on February 3, 2004, included a closed session to permit a discussion of trade secret or confidential commercial information.

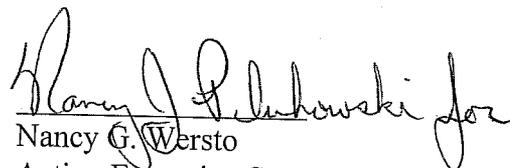
ACCOMPLISHMENTS

In the open session, the Panel discussed R2 Technologies, Inc.'s PMA for the ImageChecker CT CAD Software System. The device, a computer-aided detection (CAD) system, is designed to assist a physician in the identification of solid nodules in computerized topography (CT) images of the lung. It is intended to be a "second reader" that alerts the user to regions of interest that may have been initially overlooked. After deliberations, the Panel recommended that the application be found approvable with the following conditions: (1) a reanalysis of the data prior to approval to assess clinical significance; (2) the inclusion of strict rules for use in the labeling; (3) a requirement for formalized user training; and (4) post-market surveillance to continue collecting data on clinical significance.

Closed Committee Deliberations: On February 3, 2004, the meeting was closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future agency issues.

September 30, 2004

Date


Nancy G. Wersto
Acting Executive Secretary

Radiological Devices Panel Roster

Chairperson

Minesh P. Mehta, M.D.

Expertise: Radiotherapy; Brain or Nervous System Cancer

Term: 2/22/02 - 1/31/05

Professor & Chairman

Dept. of Human Oncology

University of Wisconsin-Madison

600 Highland Ave., K4/312 CSC

Madison, WI 53792

Executive Secretary

Nancy G., Acting Wersto

Center for Devices and Radiological Health

Office of Device Evaluation/DRAERD

9200 Corporate Blvd. HFZ-470

Rockville, MD 20850

(301) 594-1212 x144

(301) 480-4224

Wendie A. Berg, M.D., Ph.D.

Expertise: Radiology; Breast Cancer

Term: 4/21/00 - 1/31/04

Address not available

Baltimore, MD 21201

****Deborah J. Moore**

Expertise: Brain and Breast Cancer

Radiotherapy

Term: 2/1/04 - 1/31/08

Vice President, Regulatory & Clinical Affairs

Proxima Therapeutics, Inc.

2555 Marconi Drive Suite 220

Alpharetta, GA 30005--2066

*** Charles B. Burns, MSPH, RT(R)**

Expertise: Diagnostic Radiologic Physics

Term: 12/22/03 - 1/31/07

Professor, Div. of Radiologic Science

Dept. of Allied Health Sciences

Univ. of North Carolina School of Medicine

CB# 7130 Medical School Wing E

Chapel Hill, NC 27599-7130

Peter E. Shile, M.D.

Expertise: Breast Cancer

Term: 2/22/02 - 1/31/06

Medical Director

Susan G. Komen Breast Center

8800 North Route 91

Peoria, IL 61615

Emily F. Conant, M.D.

Expertise: Breast Cancer

Term: 10/8/03 - 1/31/07

Associate Professor and Chief of Breast

Imaging

Department of Radiology

University of Pennsylvania School of Medicine

3400 Spruce Street

Philadelphia, PA 19104

****Ernest L. Stern, B.S.**

Expertise: Radiology

Term: 8/13/00 - 1/31/04

Chairman and CEO

Thales Components Corp.

40 G Commerce Way

P.O. Box 540

Totowa, NJ 07511-0540

Harry K. Genant, M.D.

Expertise: Acoustics; Ultrasound

Term: 4/21/00 - 1/31/04

Prof. Radiology, Medicine, Epidemiology

University of California, San Francisco

Dept. of Radiology

505 Parnassus Ave., M392

San Francisco, CA 94143-0628

Prabhakar Tripuraneni, M.D.

Expertise: Cancer Radiotherapy

Term: 2/22/02 - 1/31/06

Head, Division of Radiation Oncology

Scripps Clinic/ Scripps Green Hospital

10666 North Torrey Pines Road, MSB1

La Jolla, CA 92037

Geoffrey S. Ibbott, Ph.D.

Expertise: Medical Physics; Radiation

Dosimetry

Term: 8/20/01 - 1/31/05

Associate Professor & Section Chief

UT M.D. Anderson Cancer Center

Dept. of Radiation Physics

1515 Holcombe Blvd., Box 547

Houston, TX 77030

Xiao-Hua A. Zhou, Ph.D.

Expertise: Clinical Trial Design; Biostatistics

Term: 7/13/04 - 1/31/08

Professor, Dept. of Biostatistics

University of Washington

1660 S. Columbian Way, Bldg 1

Seattle, WA 98108-1532

Elizabeth A. Krupinski, Ph.D.
Expertise: Radiology
Term: 7/13/04 - 1/31/08
Research Associate Professor
Dept. of Radiology
University of Arizona
1609 North Warren Bldg 211
Tucson, AZ 85724

*Consumer Representative
**Industry Representative