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Food and Drug Administration

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ORTHOPEDICS AND
REHABILITATION DEVICES
ADVISORY PANEL

Open Session
First Day

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Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, Maryland 20850

Proceedings By:

CASET Associates, Ltd.
10201 Lee Highway, Suite 160
Fairfax, VA 22030
(703) 352-0091

PANEL MEMBERS:

Barbara D. Boyan, Ph.D.
Donald Altman, D.D.S.
Cato T. Laurencin, M.D., Ph.D.
Raymond Silkaitis, Ph.D.
Harry B. Skinner, M.D., Ph.D.
Leela Rangaswamy, M.D.
Albert A. Aboulafia, M.D.
Edward Y. Cheng, M.D.
Richard D. Coutts, M.D.
Yadin David, Ph.D.
Jeremy L. Gilbert, Ph.D.
Joseph E. Hale, Ph.D.
Stephen Li, Ph.D.
Kinley Larntz, Ph.D.
Michael Urban, M.D.

FDA PARTICIPANTS:

Hany Demian, M.S.
Celia Witten, Ph.D., M.D.
Jim Dillard, M.S.
Mark Melkerson, M.S.
Ted Stevens, M.S.
Erin Keith, M.S.
Orlee Panitch, M.D.
Chang Lao, Ph.D.
Mel Seidman, Ph.D.
Harry Bushar, Ph.D.
Gary Fischman, Ph.D.

INDUSTRY REPRESENTATIVES:

J. D. Webb, Encore Orthopedics
Debbie De Los Santos, Encore Orthopedics
Joseph Longo, III, Principal Investigator
Thomas Sager, Ph.D., Statistician

TABLE OF CONTENTS

	<u>Page</u>
Panel Training:	
Conflict of Interest (Walker)	1
General and PDP training (Pluhowski)	
Reclassification Training (Shulman)	
Open Public Session	7

P R O C E E D I N G S (10:50 a.m.)

Agenda Item: Panel Training -- Conflict of
**Interest, General and PDP Training, Reclassification
Training.**

MR. DEMIAN: Good morning and welcome to the Orthopedics and Rehabilitation Devices Panel. My name is Hany Demian. I am a scientific reviewer in the Orthopedic Devices Branch as well as the executive secretary of this panel .

I would like to remind everyone that you are requested to sign in on the attendance sheets which are available at the tables by the door. You may also pick up an agenda and information about today's meeting including how to find out about future meeting dates through the advisory panel phone line and how to obtain meeting minutes or transcripts.

I will now read two statements that are required to be read into the record, the deputization of temporary voting members statement and the conflict of interest statement . Appointment to temporary voting status: Pursuant to the authority granted under the Medical Device Advisory Committee charter dated October 27, 1990, as amended April 20, 1995, I appoint the following people as voting members of the Orthopedics and Rehabilitation Devices Panel for the duration of the panel meeting on April 27 and

28: Richard Coutts, Yadin David, Jeremy Gilbert, Joseph Hale, Stephen Li, Kinley Larntz and Michael Urban. For the record, these people are special government employees and are either a consultant to this panel or a consultant or voting member of another panel under the Medical Device Advisory Committee. They have undergone the customary conflict of interest review. They have reviewed the material to be considered at this meeting. This is signed, Dr. Bruce Burlington, Director of CDRH, April 14, 1998.

This is the conflict of interest statement: The following announcement addresses the conflict of interest issues associated with this meeting and is made part of the record to preclude even an appearance of impropriety. To determine if any conflict existed, the agency reviewed the submitted agenda and all financial interests reported by the committee participants. The conflict of interest status prohibits special government employees from participating in matters that could affect their or their employees' financial interests. However, the agency has determined that participation of certain members and consultants, the need for whose services outweigh the potential conflict of interest involved is in the best interest of the government. Waivers have been granted for Drs. Cato Laurencin, Stephen Li, Albert Aboulafia, Kinley Larntz, Jeremy Gilbert and Harry Skinner because of their interests in firms which

could potentially be affected by the panel's decisions. The waivers granted for Drs. Laurencin, Li, Aboulafia, Larntz and Gilbert permit them to participate in all matters before the panel during today's session. The waivers granted for Dr. Harry Skinner allows him to participate in discussions but not vote on matters before the panel during today's session. Copies of these waivers may be obtained from the agency's Freedom of Information Act in the office room 12A15 of the Parklawn Building.

We would also like to note for the record that the agency took into consideration other matters regarding Drs . Boyan, Edward Cheng, Richard Coutts, Cato Laurencin and Stephen Li. Each reported involvement with firms at issue but on matters unrelated to the meeting's agenda. The agency has determined, therefore, that they may participate fully in today's deliberations.

In the event that the discussions involve any other products or firms not already on the agenda for which an FDA participant has a financial interest, the participant should excuse him or herself from such involvement, and the exclusion will be noted for the record. With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with any firms whose products they may wish to comment upon.

Before turning this meeting over to Dr. Boyan, I would like to introduce our distinguished panel members who are generously giving their time to help FDA in matters being discussed today and other FDA staff seated at this table . We will just go around the room, and everybody can introduce themselves and give their affiliation.

DR. BOYAN: I am Dr. Barbara Boyan. I am professor of orthopedics and director for orthopedic research at University of Texas Health Science Center at San Antonio, and my primary research interest is bone biology.

DR. COUTTS: I am Richard Coutts. I am an orthopedic surgeon in private practice in San Diego. I am the medical director of orthopedics at Sharp Health Care, and I am professor of orthopedics at the University of California San Diego. My primary interest of research is cartilage repair.

DR. CHENG: My name is Edward Cheng. I am on the faculty of the orthopedic Surgery Department at the University of Minnesota. My primary areas of interest are in oncology and adult reconstruction.

DR. ABOULAFIA: My name is Albert Aboulafia. I am a full-time member of the department of orthopedic surgery at Emory University in Atlanta. My primary areas of interest are orthopedic oncology and trauma.

DR. WITTEN: I am Celia Witten, Division Director of DGRD in ODE at CDRH.

[Laughter.]

DR. PANITCH: I am Orlee Panitch. I am the medical reviewer for orthopedics in the branch of orthopedics.

MR. STEVENS: I am Ted Stevens. I am a biomedical engineer and a reviewer in the orthopedic devices branch.

MR. WEBB: I am J. D. Webb. I am vice president of research and development at Encore Orthopedics in Austin, Texas .

MS. DE LOS SANTOS: Debbie De Los Santos. Regulatory clinical specialist at Encore Orthopedics.

MR. SAGER: I am Tom Sager. I am a professor of statistics at the University of Texas at Austin in the department of management, science and information systems. I am also codirector of the center for statistical sciences at U.T.

MR. LONGO: Joseph Longo. I am an orthopedic surgeon in solo practice in Scottsdale, Arizona, also affiliated as a clinical professor with the Phoenix integrated orthopedic training program with a primary emphasis on adult reconstruction.

MR. ALTMAN: Don Altman, dental director, Arizona Department of Health, and I am the consumer rep.

DR. HALE: I am Joseph Hale. I am a biomedical research engineer at the Minneapolis Sports Medicine Center, and my areas of interest are orthopedic biomechanics.

DR. SKINNER: My name is Harry Skinner. I am a professor of orthopedic surgery and professor of mechanical and aerospace engineering at the University of California, Irvine, and my primary interest in research is gait analysis, bone remodeling and prosthetic/bone interactions.

DR. RANGASWAMY: I am an orthopedic surgeon practicing in Boston and deputy editor for the Journal of Bone and Joint Surgery

DR. GILBERT: I am Jeremy Gilbert. I am an associate professor of biomaterials and biomedical engineering at Northwestern University. My primary interests are in biomaterials, electrochemistry and polymers.

DR. LARNTZ: I am Kinley Larntz. I am professor of statistics in the department of applied statistics in the School of Statistics at the University of Minnesota. I am a statistician. My primary research interests are in statistics .

[Laughter.]

PARTICIPANT : Surprise.

DR. LI: I am Steve Li from Department of Biomechanics and Biomaterials at the Hospital for Special

Surgery. I am the senior scientist there and professor at the University of Pennsylvania. My interests are in biomedical materials for joint replacements.

MR. DEMIAN: At this time, I would like to turn the meeting over to our chairperson, Dr. Barbara Boyan.

DR. BOYAN: Good morning. My name is Dr. Barbara Boyan. I am the chairperson for this meeting. I would like to note for the record that the voting members present constitute a quorum as required by 21 C.F.R. Part 14.

Agenda Item: Open Public Session.

We will now proceed with the open public hearing session of this meeting. I would ask at this time that all persons addressing the panel come forward and speak clearly into the microphone as the transcriptionist is dependent on this means of providing an accurate record of this meeting. We are requesting that all persons making statements during the open public hearing of the meeting disclose whether they have financial interest in any medical device company. Before making your presentation to the panel, in addition to stating your name and affiliation, please state the nature of your financial interest if any.

Is there anyone wishing to address the panel?

Since there are no other persons requesting to speak in the open public hearing, the public hearing is

closed. Please clear the room if you are here because the remainder of the meeting is closed to the public. Only previously-designated individuals who have proper identification will be permitted to stay for this closed session scheduled to discuss a PDP application. Anybody who is not specifically cleared will now leave the room.