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FOOD AND DRUG ADMINISTRATION
NATIONAL INSTITUTES OF HEALTH

Meeting of:

ORTHOPEDIC AND

REHABILITATION DEVICES

ADVISORY PANEL

Open Session

July 26, 1999

Gaithersburg Hilton Hotel
620 Perry Parkway
Gaithersburg, Maryland

Reported By:

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CATO T. LAURENCIN, MD, PhD, Professor of Chemical Engineering, Department of Chemical Engineering, Drexel University, Philadelphia, Pennsylvania

EDWARD Y. CHENG, MD, Department of Orthopaedic Surgery, University of Minnesota

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P R O C E E D I N G S

(10:45 a.m.)

AGENDA ITEM: Call to Order, Conflict of Interest.

DR. BOYAN: I call the meeting to order. While I am waiting for our executive secretary to welcome us, I would like to make a comment to the panel members.

It has just been requested that we make a special effort to speak directly into the microphones, about four to six inches from the microphone, and as we get tired during the day, that we are supposed to be reminded of that. For everybody, state your name before you speak. Okay, Mr. Demian.

DR. DEMIAN: Thank you very much. Good morning, everyone. We are ready to begin this meeting of the orthopaedic and rehabilitation devices panel.

My name is Hany Demian and I am the executive secretary of this panel, and I am a senior reviewer in the orthopaedic devices branch.

I would like to remind everyone that you are requested to sign in on the attendance sheets which are available on the tables by the doors.

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 lines, and how to obtain meeting minutes or transcripts.

I will now read two statements that are required

to be read into the record. The first one is a deputization of temporary voting member statement, and then 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 Orthopaedic and Rehabilitation Devices Panel for this meeting on July 26, 1999.

This includes Marcus Besser, Joseph Lane, John Lyons and Janice Wittes.

For the record, these people are special government employees and are consultants to the panel under the Medical Device Advisory Committee.

They have undergone customary conflict of interest review and have reviewed the material to be considered at this meeting. This is signed by Dr. Feigel.

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 the appearance of any impropriety.

To determine if any conflict existed, the agency reviewed the submitted agenda for this meeting, and all financial interests reported by the committee participants.

The conflict of interest statute prohibits special

government employees from participating in matters that could affect their or their employers' financial interests.

However, the agency has determined that the participation of certain members and consultants, the need for whose services outweigh the potential conflict of interest involved, is in the best interests of the government.

Therefore, waivers have been granted for Drs. Cato Laurencin, John Lyons and Janice Wittes, for their interest in firms that could potentially be affected by the panel's recommendations.

Copies of these waivers may be obtained from the agency's Freedom of Information Office, Room 12-A-15 of the Parklawn Building.

We would also like to note for the record that the agency took into consideration other matters concerning Drs. Edward Cheng, Michael Yaszemski, Barbara Boyan and Cato Laurencin.

Each of these panelists reported interests in firms at interest, but in matters that were unrelated to today's agenda.

The agency has determined, therefore, that they may participate fully in all discussions.

In the event that the discussions involve any other products or firms not related on the agenda, for which

the 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 the FDA in matters being discussed today, and other FDA staff seated at this table.

We will just go around the room and have everybody introduce themselves and give a little blurb about their interests and what their area of research is.

DR. BOYAN: Why don't we start with Doris Holeman?

DR. HOLEMAN: I am Doris Holeman. I am employed by Tuskegee University as the associate dean and director of the School of Nursing and Allied Health.

My research interest has been, and continues to be, patient access to health care.

DR. LYONS: My name is Con Lyons. I am an orthopaedic surgeon and biomedical engineer. I am a clinician, working in adult reconstruction in Erie,

Pennsylvania, but I have research interests and academic interests that are quite varied.

In addition, I look particularly at mechanisms of injury, failure analysis of devices and environmental failures of products.

DR. BESSER: Mark Besser, mechanical engineer, biomedical engineer. My areas of interest are in gait and walking and balance, and currently I am on faculty at Thomas Jefferson University in Philadelphia.

DR. LAURENCIN: Cato Laurencin. I am an orthopaedic surgeon and biomedical engineer, chemical engineer, on the faculty at MCP Harmon Medical School in orthopaedic surgery and also at Drexel University in chemical engineering. My interests are in biomaterials and tissue engineering.

DR. CHENG: My name is Edward Cheng. I am with the faculty at the University of Minnesota, orthopaedic surgery department. My research interests are in orthopaedic oncology and osteonecrosis.

DR. BOYAN: I am Barbara Boyan. I am the director of orthopaedic research and a professor in the department of orthopaedic biochemistry and periodontics at the University of Texas Health Science Center at San Antonio, and my interest is in the biology of bone and cartilage.

DR. YASZEMSKI: I am Michael Yaszemski. I am an

orthopaedic surgeon and a chemical engineer. I work at Mayo Clinic in Rochester, Minnesota.

My clinical interests are in spine surgery and total joint arthroplasty. My research interest is tissue engineering, specifically bone replacement, working on degradable polymer scaffolds.

DR. LANE: I am Joseph Lane. I am an orthopaedic surgeon. I am also assistant dean at the Cornell University Medical School and at the Hospital for Special Surgery.

I am an orthopaedic oncologist and I am also very interested in metabolic bone disease. My area of research is in bone regeneration.

DR. WITTES: I am Janice Wittes. I am a statistician in a little company here in D.C. called Statistics Collaborative. My primary interest is actually the design of clinical trials.

DR. WITTEN: Celia Witten, division director of DGRD in the Office of Device Evaluation at FDA.

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

DR. BOYAN: At this time, first of all, I have already introduced myself. I am Dr. Barbara Boyan, and I am the chairperson for the meeting.

I would like to note for the record that the voting members present constitute a quorum as required by 21

CFR Part 14.

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 any financial interests 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 at this time? If no one wishes to speak -- this would be general members of the public, not people from the company.

Seeing that there is no one who wants to come forward and speak, then we will close the public hearing. Please clear the room if you are a general public person, because the remainder of the meeting will be closed to the public.

Is there anybody here? Not yet? Okay, we are not going to close it for a moment here. We have an actually very important thing to do.

So, you have two extra minutes to decide whether

you want to speak. We do have something very special to do, so I am going to turn the meeting back over to Mr. Demian.

Now, it is back to me. I have been given my instructions. I would like to state that this really is an important time for me.

Dr. Holeman and I came onto the committee about the same time, and we have been through a lot together. This will be her last official act as a panel member today.

So, the FDA has done something special for you, Dr. Holeman. There is a letter here from the Commissioner of Food and Drugs, Jane Henney, and it is a really nice letter, and I would like to read it to you, and read it officially into the record.

Dear Dr. Holeman: I would like to express my deepest appreciation for your efforts and guidance during your term as the consumer representative member of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

The success of this committee's work reinforces our conviction that responsible regulation of consumer products depends greatly on the participation and advice of the non-governmental health community.

In recognition of your distinguished service to the Food and Drug Administration, I am pleased to present you with the enclosed certificate.

The enclosed certificate is fancy. So, now, Mr. Dillard, will you hand over the fancy enclosed certificate?

MR. DILLARD: Yes, thank you, Dr. Boyan. Also, on behalf of the FDA and certainly the Office of Device Evaluation, and particularly our division, the division of general and restorative devices, I would like to personally extend our gratitude also to you, Dr. Holeman, whose service has really been invaluable over the last, I believe, four years.

I don't know if we are coming up on four years here. I believe that that is probably the date. On behalf of all of us, we certainly appreciate the work that you have given us on this advisory committee.

More important, I think really, from the standpoint of the consumer and the consumer public that you represent and have represented very adequately and more than adequately, excellently I should say, over the last four years, I know I personally will miss having you on the advisory committee and I know Dr. Witten feels the same.

So, on behalf of the division of general and restorative devices, and even more important, the Food and Drug Administration, I would just like to read this plaque.

It is a certification of appreciation for Doris S. Holeman, PhD, in recognition of distinguished services,

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

The term was from May 12, 1996 to August 31, 1999. It is signed by our acting center director at the time, Dr. Elizabeth Jacobson, and the Commissioner of Food and Drugs, Jane Haney. Thank you, Dr. Holeman.

[Applause.]

DR. BOYAN: Okay, one last chance to speak to us before we close the open session. Okay, since there are no other requests to speak in the open public hearing, the public hearing is closed.

Now, again, we ask the room to be cleared of anybody who is here for the public session only, 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.

[Whereupon, at 10:55 a.m., the public session was adjourned.]