

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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HEMATOLOGY AND PATHOLOGY DEVICES ADVISORY PANEL

OPEN PUBLIC MEETING

+ + + + +

WEDNESDAY,

DECEMBER 15, 1999

+ + + + +

The meeting took place at 9:00 a.m. in Conference Room 020B of the Center for Devices and Radiological Health, 9200 Corporate Boulevard, Rockville, Maryland, Dr. Diane D. Davey, Acting Panel Chairperson, presiding.

Present:

- DIANE D. DAVEY, M.D., Acting Chairperson
- GEORGE G. BIRDSONG, M.D., Temporary Voting Member
- JUAN C. FELIX, M.D., Voting Member
- MARY NIELSEN, M.D., Voting Member
- DIANE H. NORBACK, M.D., Temporary Voting Member
- SIMON OGAMBDI, Ph.D., Voting Member
- MARGARET S. PEPE, Ph.D., Temporary Voting Member
- ANDREW A. RENSHAW, M.D., Temporary Voting Member
- ELLEN S. ROSENTHAL, M.S., Consumer Representative
- ROBERT L. WILLIAMS, JR., M.D., Temporary Voting Member

Also Present:

MICHELLE Y. CLARK-STUART, MGA, MT(ASCP), Executive Secretary

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Sponsor Presenters:

BINU L. DHINDSA  
ROBERT P. HIRSCH, Ph.D.  
DAN MACLEAN, Ph.D.  
SYDNEY BENNETT REIMER, M.D.

FDA Staff:

STEVEN GUTMAN, M.D.  
GREG CAMPBELL, Ph.D.  
JOHN DAWSON  
LOUISE MAGRUDER

I-N-D-E-X

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1 P-R-O-C-E-E-D-I-N-G-S

2 (9:06 a.m.)

3 MS. STUART: Good morning, everyone.

4 My name is Michelle Stuart and I have a  
5 conflict of interest statement that has to be read  
6 before we start our hematology and pathology devices  
7 panel meeting today which is December 15, 1999.

8 The following announcement addresses  
9 conflict of interest issues associated with this  
10 meeting and is made a part of the record to preclude  
11 even the appearance of an impropriety. To determine  
12 if any conflict existed the Agency reviewed the  
13 submitted agenda and all financial interests reported  
14 by the Committee participants.

15 The conflict of interest statutes prohibit  
16 special government employees from participating in  
17 matters that could affect their own or their  
18 employer's financial interest. However, the Agency  
19 has determined that participation of certain members  
20 and consultants, the need for whom services outweigh  
21 the potential conflict of interest involved is in the  
22 best interest of the government.

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1           We would like to note for the record that  
2 the Agency took into consideration certain matters  
3 regarding Dr. Diane Davey, Dr. George Birdsong and Dr.  
4 Juan Felix. Each of these panelists reported past or  
5 current interest in firms at issue on matters not  
6 relating to what is being discussed today. Since  
7 these interests are not related to the specific issue  
8 before the panel, the Agency has determined that they  
9 may participate fully in today's discussions.

10           In the event that the discussions involve  
11 any other products or firms not already on the agenda  
12 for which an FDA participant has a financial interest,  
13 the participant should excuse him or herself from such  
14 involvement and the exclusion will be noted for the  
15 record.

16           With respect to all other participants, we  
17 ask in the interest of fairness that all persons  
18 making statements or presentations disclose any  
19 current or previous financial involvement with any  
20 firm whose products they may wish to comment on.

21           Next I will read the appointment to  
22 temporary voting status. Pursuant to the authority

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1 granted under the Medical Devices Advisory Committee  
2 charter dated October 27, 1990, and as amended, August  
3 18, 1999, I appoint the following individuals as  
4 voting members of the Hematology and Pathology Devices  
5 for this meeting on 15 December 1999: Dr. George  
6 Birdsong, Dr. Diane Norback, Dr. Margaret Pepe, Dr.  
7 Andrew Renshaw, Dr. Robert Williams, Dr. Diane Davey  
8 and Diane Davey has graciously considered being our  
9 acting chairperson for today. Pursuant to the  
10 authority granted under the Medical Devices Advisory  
11 Committee Charter, dated October 27, 1990, and as  
12 amended, August 18, 1999, I appoint the following  
13 individuals as voting members of the Hematology and  
14 Pathology Devices for this meeting on 15 December  
15 1999: Dr. George Birdsong, Dr. Diane Norback, Dr.  
16 Margaret Pepe, Dr. Andrew Renshaw, Dr. Robert  
17 Williams, Dr. Diane Davey and Diane Davey has  
18 graciously considered being our acting chairperson for  
19 today.

20 For the record, these individuals are  
21 special government employees and consultants to this  
22 panel or other panels under the Medical Devices

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1 Advisory Committee. They have undergone the customary  
2 conflict of interest review and have reviewed the  
3 material to be considered at this meeting. Signed  
4 David Feigal, M.D., Director for the Center of Devices  
5 and Radiological Health.

6 Now I will introduce Dr. Diane Davey, our  
7 Acting Chairperson for the duration of this meeting  
8 and the rest of the panel members will please  
9 introduce themselves as we go around the table.

10 Thank you.

11 CHAIRPERSON DAVEY: Thank you.

12 I'm Diane Davey. I'm a cytopathologist,  
13 Director of Cytology at the University of Kentucky in  
14 Lexington and I'd just like to ask everybody to  
15 introduce themselves and make sure that you speak into  
16 the microphone when you're making any comments for the  
17 recording.

18 DR. NIELSEN: I'm Dr. Mary Nielsen, a  
19 cytopathologist in practice in Wichita, Kansas. I'm  
20 in a private practice situation.

21 DR. FELIX: My name is Juan Felix. I'm a  
22 cytopathologist and gynecological pathologist at the

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1 University of Southern California at the Los Angeles  
2 County Hospital.

3 DR. PEPE: I'm Margaret, Department of  
4 Biostatistics at the Fred Hutchinson Cancer Research  
5 Center in Seattle.

6 DR. GUTMAN: I'm Steve Gutman, I'm the  
7 Director of the Division of Clinical Laboratory  
8 Devices, FDA.

9 DR. BIRDSONG: I'm George Birdsong. I'm a  
10 cytopathologist at Emory University, Atlanta and I  
11 work at Grady Hospital in Atlanta.

12 DR. WILLIAMS: Good morning, I'm Rob  
13 Williams. I'm a practicing OB/GYN in Atlanta,  
14 Georgia. I also am the Chairman of OB/GYN at  
15 Southwest Hospital in Atlanta and I have a teaching  
16 appointment at Morehouse School of Medicine.

17 DR. NORBACK: I'm Diane Norback from the  
18 University of Wisconsin. I'm a hematopathologist.

19 DR. RENSHAW: I'm Dr. Andrew Renshaw. I'm  
20 from Miami, Florida. I work at the Baptist Hospital  
21 in Miami. I'm a cytopathologist there.

22 MS. ROSENTHAL: I'm Ellen Rosenthal. I'm

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1 a free-lance writer with a background in engineering.

2 DR. OGAMBDI: Simon Ogambdi, Chair, Health  
3 Sciences, Florida Atlantic University, Florida.

4 CHAIRPERSON DAVEY: All right, thank you.

5 I guess going to the agenda, I guess we're going to  
6 the open public hearing, I'm not sure. Is somebody  
7 going to be making a comment for that?

8 MS. STUART: This is Michelle Stuart. Is  
9 either Mr. Kessler or Mr. Gross here for the  
10 presentation?

11 (Pause.)

12 In view of the fact that they're not here,  
13 we can go on.

14 CHAIRPERSON DAVEY: Well, then we can make  
15 up a little time. I will say I have a plane to catch  
16 at 6 o'clock and I have to absolutely be back. Okay,  
17 I guess we'll go into the closed deliberations. If  
18 there's any public observers, I guess they're supposed  
19 to leave. I don't think there is anybody here though.

20 (Whereupon, at 9:15 a.m., the open public  
21 hearing was concluded.)

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