

at

ATDEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

**CIRCULATORY SYSTEM DEVICES PANEL**  
OPEN SESSION

Thursday, December 4, 1997

8:15 a.m.

Room 20B  
9200 Corporate Boulevard

MILLER REPORTING COMPANY, INC.  
507 C Street, N.E.  
Washington, D.C. 20002  
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at

Rockville, Maryland

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at

PARTICIPANTS

Anne B. Curtis, M.D., Chairperson  
John E. Stuhlmuller, M.D., Executive Secretary

VOTING MEMBER

Tony W. Simmons, M.D.

CONSUMER REPRESENTATIVE

David A. Gooray, M.D.

CONSULTANTS

Kent F. Bailey, Ph.D.  
Jeffery A. Brinker, M.D.  
Michael D. Crittenden, M.D.  
Michael J. Domanski, M.D.  
Cynthia M. Tracy, M.D.

FDA

Thomas J. Callahan, Ph.D.

at

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P R O C E E D I N G S

DR. CURTIS: I would like to go ahead and call this meeting of the Circulatory System Devices Panel to order. First, we have a conflict of interest statement.

**Conflict of Interest Statement**

DR. STUHLMULLER: The following announcement addresses the issue of conflict of interest issues associated with this meeting and is made a part of the record to preclude even the appearance of an 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 statutes prohibit special government employees from participating in matters that could affect their or their employers' 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.

A full waiver has been granted to Dr. Tony Simmons for his financial interest in firms at issue that could potentially be affected by the panel's decisions. Copies of this waiver may be obtained from the agency's Freedom of

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Information Office, Room 12A-15 of the Parklawn Building.

We would also like to note for the record that the agency took into consideration other matters regarding Dr. Anne Curtis, Jeffery Brinker, Cynthia Tracy and Tony Simmons. Each of these panelists reported interest in firms at issue on matters not related to what is being discussed today. Since these interests are not related to this specific issue before the panel, the agency has determined that they may participate fully in today's discussions.

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 participants should exclude themselves from such involvement and their 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 firm whose products they may wish to comment on.

#### **Old Business**

DR. CURTIS: There is no old business before the panel that I am aware of.

#### **New Business**

DR. CURTIS: In terms of new business, no one has

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previously requested time to speak at the open public hearing. I would like to know if there is anybody in the audience. We were going to wait because there are some people missing, but we can go ahead and do the introductions now, then.

We will go around the table. I am Anne Curtis. I am an electrophysiologist at the University of Florida in Gainesville, Florida.

DR. TRACY: Cindy Tracy. I am an electrophysiologist at Georgetown University.

DR. BAILEY: Kent Bailey, biostatistician at Mayo Clinic.

DR. CRITTENDEN: Mike Crittenden, cardiac surgeon from the West Roxbury V.A.

DR. GOORAY: David Gooray, cardiologist, Washington, D.C.

DR. SIMMONS: Tony Simmons, Wake Forest University. I am an electrophysiologist.

DR. DOMANSKI: Mike Domanski. I am a cardiologist at the National Heart Lung and Blood Institute.

DR. BRINKER: Jeff Brinker, cardiologist, Johns Hopkins.

DR. CALLAHAN: Tom Callahan, Director of Cardiovascular Respiratory.

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DR. CURTIS: Thank you.

**Open Public Hearing**

DR. CURTIS: No one has requested time to speak at the open public hearing previously. Is there anybody here who wanted to speak? Then, there isn't any business for the open public hearing. That means we will be moving on to the closed session which means, apparently, that we all need to file out and resign in.

We are going to have to exit the room, resign in and come in in order to start the closed session.

[Whereupon, at 8:20 a.m., the proceedings were adjourned.]

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