

# AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE  
89th Meeting – April 26-27, 2007  
Hilton Hotel, Washington, DC North / Gaithersburg  
620 Perry Parkway, Gaithersburg, MD 20877

Thursday, April 26, 2007

2:00 p.m. Opening Remarks, Frederick P. Siegal, M.D., Medical Director, Comprehensive HIV Center, Saint Vincent's Catholic Medical Centers, New York, NY, Chairperson, BPAC

Statement of Conflict of Interest, Acknowledgement of New Members, Announcements

2:10 p.m. Topic I: Issues Related to Implementation of Blood Donor Screening for Infection with *Trypanosoma cruzi* and the Potential Transmission of *Trypanosoma cruzi* by Human Cells, Tissue and Cellular and Tissue-Based Products

A. Introduction and Issues Related to Implementation of Blood Donor Screening for Antibodies to *T. cruzi* Infection, Robert Duncan, Ph.D., DETTD, OBRR, FDA (20')

B. Introduction of Issues Related to the Potential Transmission of *T. cruzi* by Human Cells, Tissues and Cellular and Tissue-Based Products, Melissa A. Greenwald, M.D., CDR, USPHS, DHT, OCTGT, FDA (20')

C. Ortho *T. cruzi* ELISA Test System Experience, Susan Stramer, Ph.D., American Red Cross (20')

D. Public Health Impact of Donor Screening for *T. cruzi* Infection, Susan P. Montgomery, D.V.M., M.P.H., Centers for Disease Control and Prevention (20')

E. Potential Strategies for Targeted Testing for *T. cruzi* Infection in Repeat Donors, Michael P. Busch, M.D., Ph.D./ Brian Custer, Ph.D., M.P.H., Blood Systems Research Institute (30')

4:15 p.m. Break

4:30 p.m. Open Public Hearing

5:00 p.m. Open Committee Discussion

F. Questions for the Committee

G. Committee Discussion

6.00 p.m. Adjournment

Friday, April 27, 2007

8:00 a.m. Committee Updates

- Summary of August 30-31, 2006 Meeting of the DHHS Advisory Committee on Blood Safety and Availability, Jerry Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability (10')
- Summary of December 15, 2006 Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee and FDA's Risk Communication on Plasma Derived Factor VIII and Factor XI, Dorothy Scott, M.D., DH, OBRR, FDA and Mark Weinstein, Ph.D., OBRR, FDA (20')
- Summary of September 25-26, 2006 FDA Workshop on Molecular Methods in Immunohematology, Sheryl Kochman, DBA, OBRR, FDA (15')

8:45 a.m. Topic II: Transfusion Related Acute Lung Injury (TRALI)

- A. Introduction, Alan Williams, Ph.D., DBA, OBRR, FDA (10')
- B. Clinical and Laboratory Aspects of TRALI, David F. Stroncek, M.D., National Institutes of Health (25')
- C. Current Use of Transfusable Plasma, Ravindra Sarode, M.D., University of Texas Southwestern Medical Center (20')
- D. Review of REDS-II LAPS Study on HLA and Granulocyte Antibody Prevalence in Blood Donors, Steven H. Kleinman, M.D., University of British Columbia (20')
- E. American Red Cross Experience with TRALI, Richard J. Benjamin, M.D., Ph.D., American Red Cross (15')
- F. America's Blood Centers Experience with TRALI, Celso Bianco, M.D., America's Blood Centers (15')

10:30 a.m. Break

10:45 a.m. Open Public Hearing

11:15 a.m. Open Committee Discussion

- F. Questions for the Committee
- G. Committee Discussion

12:15 p.m. Lunch

1:15 p.m. Topic III: Issues Related to Implementation of West Nile Virus Testing

- A. Update on WNV Epidemic 2006, Eileen Farnon, M.D., Centers for Disease Control and Prevention (15')
- B. Issues for Testing, Maria Rios, Ph.D., DETTD, OBRR, FDA (25')
  - i. Approaches to Confirmatory Testing
  - ii. Donor and Unit Management

iii. Approaches to ID-NAT Trigger

C. Data in Support of the Current ID-NAT Triggers, Susan Stramer, Ph.D., American Red Cross (20')

2:15 p.m. Open Committee Discussion

3:15 p.m. Adjournment