

DRAFT 3/13/2002 - INFORMATIONAL ONLY

BLOOD PRODUCTS ADVISORY COMMITTEE  
72nd Meeting - March 14-15, 2001  
Gaithersburg Holiday Inn  
2 Montgomery Village Avenue  
Gaithersburg, MD 20877

Thursday, March 14, 2002

8:00 a.m. Welcome, Statement of Conflict of Interest,  
Announcements

8:10 a.m. Committee Updates

- Nucleic Acid Testing for Whole Blood, Including Standards for HIV-1 and HCV RNA - Indira Hewlett, Ph.D.
- Nucleic Acid Testing for Parvovirus B19 - Mei-ying Yu, Ph.D.
- Nucleic Acid Testing for Hepatitis A Virus - Gerardo Kaplan, Ph.D.
- Draft "Guidance for Industry on Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts" - Andrew Dayton, M.D., Ph.D.
- Announcement of Planned FDA Workshops

9:45 a.m. BREAK

10:00 a.m. *Open Committee Discussion*

I. Emergency Preparedness - Informational Presentation

- A. OBRR Strategic Plan - Richard Lewis, Ph.D.
- B. Supply Management - AABB Task Force
- C. Summary of PHS Advisory Committee on Blood Safety and Availability Meeting, January 31-February 1, 2002 - Stephen Nightingale, M.D.
- D. OBRR Divisional Initiatives
  - Division of Hematology - Mark Weinstein, Ph.D.
  - Division of Emerging and Transfusion Transmitted Diseases - Hira Nakhasi, Ph.D.
  - Division of Blood Applications - Alan Williams, Ph.D.

12:30 p.m. OPEN PUBLIC HEARING

1:00 p.m. *Open Committee Discussion*

E. Committee Discussion

1:30 p.m. LUNCH

2:30 p.m. *Open Committee Discussion*

II. Discussion on Percutaneous Exposure of Blood and Plasma Donors: Tattoos and Body Piercing

- Applications,  
Viral  
Hepatitis,  
for  
Who  
Blood
- A. Introduction and Background - Alan Williams, Ph.D., Director, Division of Blood OBRR, FDA
  - B. Epidemiological Studies Evaluating Risk of Hepatitis Infection from Tattoos and Body Piercing - Miriam Alter, Ph.D., Chief, Epidemiology Branch, Division of Viral CDC
  - C. Prevalence and Characterization of Deferrals Tattoo, Accupuncture and Skin/Body Piercing Fail to Self-Defer - Sharyn Orton, Ph.D. Regulatory Project Manager, Division of Applications
    - i) Donor Deferral Estimates
    - ii) REDS Survey Data

3:30 p.m. BREAK

3:45 p.m. OPEN PUBLIC HEARING

4:45 p.m. *Open Committee Discussion*

- D. Questions for the Committee - Alan Williams, Ph.D.
- E. Committee Discussion and Recommendations

5:30 p.m. RECESS (until 8:00 a.m., Friday, March 15, 2002)

Friday, March 15, 2002

8:00 a.m. *Open Committee Discussion*

Period III. Review of Data Supporting Extension of Dating for Platelets

- A. Introduction and Background -Jaro Vostal, M.D., Ph.D., Chief, Laboratory Of Cellular Hematology, Division of Hematology OBRR, CBER
- B. Extension of Platelet Storage: Fact or Fantasy - Sherrill Slichter, M.D., Executive Vice President of Research, Puget Sound Blood Center, Seattle, WA
- C. Safer, Cheaper and Just as Good: Making Sterile, 7-Day Platelets a Reality - James

AuBuchon, M.D., Professor and Chair of  
Pathology, Dartmouth-Hitchcock  
Medical Center, Lebanon, NH

9:30 a.m. OPEN PUBLIC HEARING

10:00 a.m. BREAK

10:30 a.m. *Open Committee Discussion*

D. Committee Discussion

11:30 a.m. LUNCH

12:30 p.m. *Open Committee Discussion*

Tissue IV. Bacterial and Fungal Contamination of Human  
Intended for Transplantation

A. Introduction and Background - Ruth Solomon,  
M.D., Director, Human Tissue Staff, OBRR,  
CBER

B. Microbial Contamination and Cross  
Contamination Concerns During Processing of  
Tissue - Mary Malarkey, Director, Division  
of Case Management, OCBQ, CBER, FDA

C. Preliminary Findings From an Investigation of  
Allograft-Associated Infections - Marion A.  
Kainer, MBBS, MPH, FRACP, Epidemic  
Intelligence Service Officer, Division of  
Healthcare Quality Promotion, NCID, CDC

D. Reducing the Risk of Tissue Transplant-  
Transmitted Bacterial and Fungal Infections:  
Tissue Banks Perspective - D. Ted Eastlund,  
M.D., Head, Division of Transfusion  
Medicine, Dept. of Lab Medicine, University  
of Minnesota Medical School

E. Adverse Reactions (Endophthalmitis) After  
Corneal Transplantation: Eye Banks  
Perspective - Michael A. Lemp, M.D., EBAA

2:30 p.m. OPEN PUBLIC HEARING

3:00 p.m. *Open Committee Discussion*

F. Committee Discussion

4:00 p.m. ADJOURNMENT