

DRAFT AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE  
67<sup>th</sup> Meeting - September 14-15, 2000  
Gaithersburg Hilton, 620 Perry Parkway  
Gaithersburg, MD 20877

**Thursday, September 14, 2000**

8:00 a.m. Statement of Conflict of Interest

8:05 a.m. Welcome and Opening Remarks

8:10 a.m. **Committee Updates**

- **Summary of PHS Advisory Committee on Blood Safety and Availability Meeting, August, 24 2000 - Stephen Nightingale, M.D.**
- **Factor VIII & vWF Standards - Andrew Chang, Ph.D./Nancy Kirschbaum, Ph.D.**
- **Blood Supply Update - Paul McCurdy, M.D**

9:00 a.m. *Open Committee Discussion*

**I. HIV p24 Antigen Testing of Plasma for Fractionation  
- Potential Criteria for Discontinuation**

- A. Introduction and Background - Indira Hewlett, Ph.D., Chief, Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases
- B. Presentation - Michael Busch, M.D., Ph.D., Blood Centers of the Pacific, Sacramento, CA

9:30 a.m. **OPEN PUBLIC HEARING**

- Presentation - NGI - Andrew Conrad, Ph.D.
- Presentation - Alpha Therapeutics
- Presentation - Aventis - Charles Watson, Ph.D.
- Presentation - Bayer - Barbara Masecar
- Presentation - Baxter
- Presentation - American Red Cross - Susan Stramer, Ph.D
- Presentation - Abbott Laboratories - Gerald Schochetman, Ph.D.
- Presentation - Chiron Corporation - Chyang Fang, Ph.D.

11:15 a.m. **BREAK**

11:45 a.m. ***Open Committee Discussion***

- C. Question(s) for the Committee - Indira Hewlett, Ph.D.
- D. Committee Discussion and Recommendations

12:45 p.m. **LUNCH**

1:45 p.m. ***Open Committee Discussion***

**II. Deferral, As Blood or Plasma Donors, of Males Who Have Had Sex with Males**

- A. Introduction and Background - Andrew Dayton, M.D., Ph.D., Medical Officer, DETTD
- B. Epidemiology Presentation - Michael Busch, M.D., Ph.D., Blood Centers of the Pacific, CA
- C. Risk Assessment Model and Proposed Policy - Andrew Dayton, M.D., Ph.D.

3:15 p.m. **BREAK**

3:30 p.m. **OPEN PUBLIC HEARING**

4:00 p.m. ***Open Committee Discussion***

- D. Question(s) for the Committee - Andrew Dayton, M.D., Ph.D.
- E. Committee Discussion and Recommendations

5:00 p.m. **RECESS** (until 8:00 a.m., Friday, September 15, 2000)

**Friday, September 15, 2000**

8:00 a.m. Committee Updates

- **Summary of Workshop on Recruiting Blood Donors - Successful Practices, July 6-7, 2000 - Gilliam Conley**
- **Summary of Workshop on Hemopoietic Cells From Cord Blood - Ellen Lazarus, M.D.**
- **Summary of Public Meeting on Regulation of Bone Products - Ruth Solomon, M.D.**
- **Summary of Joint Transmissible Spongiform Encephalopathies & Vaccines and Related Biological Products Advisory Committees Meeting - David Asher, M.D.**
- **Update on Rapid HIV Test Approval Requirements and Standards -**

Kimber L. Poffenberger, Ph.D.

8:40 a.m. **Open Committee Discussion**

**III. Current Utility of Screening Blood Donors for Antibodies to Syphilis**

- A. FDA Framework - Chiang Syin, Ph.D.
- B. Background on Clinical Syphilis - Lauri Markowitz, M.D., CDC
- C. Background on Diagnostic Testing for Syphilis - Roger Y. Dodd, Ph.D., ARC
- D. Syphilis Surveillance and Bloodborne Transmission - Lauri Markowitz, M.D., CDC
- E. American Red Cross NAT Donor Study - Sharyn Orton, Ph.D., ARC
- F. REDS Study of Syphilis Screening as a Surrogate Test - Alan Williams, Ph.D., ARC
- G. Maricopa County STD Study - Lauri Markowitz, M.D., CDC
- H. CDC Proposed Studies - Drs. Hsi Liu/Stephen Morse, CDC

10:45 a.m. **BREAK**

11:00 a.m. **OPEN PUBLIC HEARING**

11:30 a.m. **Open Committee Discussion**

- H. FDA Position - Martin Ruta, J.D., Ph.D.
- I. Question(s) for the Committee
- J. Committee Discussion and Recommendations

12:30 p.m. **LUNCH**

1:30 p.m. **IV. Classification of HLA Devices**

- A. FDA Presentation of the Issue - Sheryl Kochman, Chief, Devices Review Branch, Division of Blood Applications
- B. Third Party Review Program - Eric Rechen, ODE, CDRH

1:45 p.m. **OPEN PUBLIC HEARING**

**Industry Presentations**

2:15 p.m. **Open Committee Discussion**

- C. Charge to the Committee - Executive Secretary, BPAC
- D. Question(s) for the Committee - Sheryl Kochman
- E. Committee Discussion and Recommendations

2:45 p.m. **Open Committee Discussion**

**V. Report of Intramural Site Visit: Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases**

A. Introduction and Overview

1. Neil Goldman, Ph.D., Associate Director for Research, CBER
  
2. John Finlayson, Ph.D., Associate Director for Science, OBRR
  
3. Hira Nakhasi, Ph.D., Director, Division of Emerging and Transfusion Transmitted Diseases
  
4. Indira Hewlett, Ph.D., Chief, Laboratory of Molecular Virology, DETTD
  
5. Subhash Dhawan, Ph.D., Laboratory of Molecular Virology, DETTD

3:30 p.m. **CLOSED COMMITTEE DISCUSSION**

- B. Committee Discussion and Recommendations

4:00 p.m. **ADJOURNMENT**