

June 13, 2000

DRAFT AGENDA
BLOOD PRODUCTS ADVISORY COMMITTEE
66th Meeting - June 15-16, 2000
Holiday Inn, Silver Spring
8777 Georgia Avenue, Silver Spring, MD

Thursday, June 15, 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, April 25-26, 2000, Stephen Nightingale, M.D.**
- **Summary of Workshop on Plasticizers: Scientific Issues in Blood Collection, Storage, and Transfusion, October 18, 1999 - Jaroslav Vostal, M.D., Ph.D.**
- **Report on Blood Supply Monitoring - Paul McCurdy, M.D.**
- **Summary of Transmissible Spongiform Encephalopathies Advisory Committee Meeting, June 1-2, 2000 - David Asher, M.D.**

9:30 a.m. *Open Committee Discussion*

I. Plasma Pool Screening by Nucleic Acid Tests for Hepatitis A Virus

- A. Introduction and Background - Robin Biswas, M.D., Chief, Hepatitis Branch, Division of Emerging Transfusion Transmitted Diseases
- B. Regulatory Options for HAV NAT - Sheryl Kochman, Chief, Devices Branch, DBA
- C. Review of History of Hepatitis A Transmitted Transfusion, Mahmood Farshid, Ph.D., Scientist, Division of Hematology
- D. Hepatitis A Virus: Epidemiology/Clinical Implications/Prophylaxis - Stephen Feinstone, M.D., Chief, Laboratory of Hepatitis Viruses, Division of Viral Products, OVRP
- E. HAV Transmission by Factor VIII Concentrates - Dr. Michael Chudy, Paul Ehrlich Institute

10:30 a.m. **BREAK**

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

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

- F. FDA Perspective and Questions - Robin Biswas, M.D., Medical Officer, DETTD
- G. Committee Discussion and Recommendations

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

1:30 p.m. ***Open Committee Discussion***

II. Development of Rapid HIV tests

- A. Background and Introduction - Kimber Lee Poffenberger, Ph.D., Regulatory Scientist, DETTD
 - B. Presentation - 1LT Hassan S. Zahwa, M.S. Department of Defense
 - C. Presentation - Nancy A. Wade, M.D., M.P.H., Department of Health
 - D. Presentation - Robert S. Janssen, M.D., Director, Division of HIV/AIDS Prevention, Centers for Disease Control
 - E. Presentation - Bernard M. Branson, M.D., Centers for Disease Control and Prevention
- NYS

2:30 p.m. **OPEN PUBLIC HEARING**

3:30 p.m. **BREAK**

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

- F. Questions for the Committee - Kimber Poffenberger, Ph.D.
- G. Committee Discussion and Recommendations

5:00 p.m. **Recess** (until 9:00 a.m. Friday, June 16, 2000)

Friday, June 16, 2000

9:00 a.m. **Committee Updates**

- Update on Requirement for Syphilis Testing - Martin Ruta, Ph.D., J.D.
- Regulation of HIV Drug Resistance Tests - Martin Ruta, Ph.D., J.D.

- Risk of HCV to Sexual Partners - Robin Biswas, M.D.
- Relative Sensitivity of HBsAg and HBV NAT Tests - Robin Biswas, M.D.

9:30 a.m. **Open Committee Discussion**

**III. Proposed FDA Guidance on Universal Leukoreduction:
Current Thinking**

A. Introduction and Background - Jong-Hoon Lee,
M.D., Chief, Blood and Plasma Branch, DBA

10:30 a.m. **OPEN PUBLIC HEARING**

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

B. Committee Discussion and Recommendations

12:30 p.m. **ADJOURNMENT**