

March 8, 2000

DRAFT

DRAFT AGENDA
BLOOD PRODUCTS ADVISORY COMMITTEE
65th Meeting - March 16-17, 2000
Holiday Inn, Silver Spring
8777 Georgia Avenue, Silver Spring, MD

Thursday, March 16, 2000

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

8:05 a.m. Welcome and Opening Remarks

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

• **Summaries of Recent Workshops:**

1. Bacterial Contamination of Platelets - Chiang Syin, Ph.D.
2. Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes - Paul Aebersold, Ph.D.
3. Implementation of Universal Leukoreduction - Jong-Hoon Lee, M.D.
4. NIH Workshop on Parvovirus B19 - Thomas Lynch, Ph.D.

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

I. Indeterminate HIV-1 Western Blots With Only Non-viral Bands

- A.** Introduction and Background - Paul Mied, Ph.D., Deputy Director, Division of Emerging and Transfusion Transmitted Diseases, OBRR
- B.** Data from Clinical Studies - Christopher Bentsen, Genetic Systems Corp., Redland, WA
- C.** ARC Experience with Indeterminate Blood Donors Stramer, Ph.D., American Red Cross, Rockville, MD
- D.** Significance of HIV Indeterminates Western Blot Results - Michael Busch, M.D., Ph.D., Blood Centers of the Pacific, San Francisco, CA
- E.** Risk of False Negatives - Thomas L. Hearn, M.D., Centers for Disease Control and Prevention, Atlanta, GA

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

(Statements from Bio-Rad, Calypte, Epitope)
(Statements from AABB, ABC, APHL)

11:00 a.m. **BREAK**

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

F. Questions for the Committee
G. Committee Discussion and Recommendations

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

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

II. History of Hepatitis

- A. Introduction and Background - Robin Biswas, M.D.,
Division of Emerging and Transfusion Transmitted
Diseases
- B. Presentation - Ian Williams, M.D., Hepatitis
Branch, Centers for Diseases Control and
Prevention
- C. Presentation - Harvey Alter, M.D., Chief,
Infectious Diseases, Department of Transfusion
Medicine, NIH

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

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

D. Questions for the Committee
E. Committee Discussion and Recommendations

3:30 p.m. **III. HBV Nucleic Acid Testing**

- A. Introduction and Background - Edward Tabor, M.D.
- B. Presentation - Kusuya Nishioka, M.D. Japanese Red
Cross Blood Center
- C. Presentation - Susan Stramer, Ph.D., American Red
Cross
- D. Scientific Presentations - Charles Watson, Ph.D.,
Centeon
- E. Scientific Presentation - Andrew Conrad, Ph.D.,

NGI

4:30 p.m. OPEN PUBLIC HEARING

5:00 p.m. *Open Committee Discussion*

F. Committee Discussion and Recommendations

6:00 p.m. Recess (until 8:00 a.m. Friday, March 17, 2000)

Friday, March 17, 2000

8:00 a.m. Committee Updates

- Summary of January 2000 PHS Advisory Committee Meeting on Blood Safety and Availability - Stephen Nightingale, M.D.
- CJD Policy - Dorothy Scott, M.D.
- HCV Lookback Guidance - Paul Mied, Ph.D.
- Post Donation Information Algorithm - Edward Tabor, M.D.
- IGIV Clinical Endpoints - Basil Golding, M.D.

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

IV. Blood Action Plan: Supply Issues - Informational
- Mary Gustafson, Director, Division of Blood Applications

9:30 a.m. OPEN PUBLIC HEARING

10:00 a.m. BREAK

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

V. Donor Deferral Issues Related to Xenotransplantation

A. Introduction and Background - Andrew Dayton, M.D., Ph.D., Laboratory of Molecular Virology, DETTD

B. Questions for the Committee

11:30 a.m. **PUBLIC HEARING**

12 Noon **Open Committee Discussion**

C. Committee Discussion and Recommendations

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

1:30 p.m. **VI. Report of Intramural Site Visit: Laboratory of
Plasma Derivatives, Division of Hematology**

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. Mark Weinstein Ph.D., Director, Division of Hematology
4. Summary of Laboratory of Plasma Derivatives - Basil Golding, M.D., Chief, Laboratory of Plasma Derivatives, DH

3:00 p.m. **CLOSED COMMITTEE DELIBERATIONS**

3:30 p.m. **ADJOURNMENT**