



**Advisory Committee
on
Blood Safety and Availability
Department of Health and Human Services**

Fortieth Meeting, June 7 & 8, 2011

The National Institute of Health

Building 31 6C Room 6
9000 Rockville Pike
Bethesda, MD 20892
Phone: (301) 402-7836

Tuesday, June 7, 2011

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| 08:00 | Doors Open | Open to the Public |
| 08:30 | Call to Order | Chairman |
| 08:35 | Roll Call/Conflict of Interest | Jerry A. Holmberg, PhD Executive Secretary |
| 08:40 | New Members Oath | Howard K. Koh, M.D., MPH Assistant Secretary for Health |
| 09:00 | Assistant Secretary for Health's Charge to the Committee | Howard K. Koh, M.D., MPH Assistant Secretary for Health |

Committee Updates

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|-------|--|---------------------------|
| 09:30 | Blood Products Advisory Committee Update | Jennifer Scharpf - FDA |
| 09:45 | Biovigilance Update | Jerry A. Holmberg, PhD |
| 10:00 | FDA/PPTA/HHS Workshop Summary: Risk Mitigation Strategies to Address Procoagulant Activity in Immune Globulin Products | Dorothy Scott, M.D. – FDA |
| 10:15 | Break Time | |

Adverse Events and Reactions Update

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| 10:30 | FDA Fatality & Product Deviation Reports – An Update | Gilliam Conley- FDA |
| 10:45 | Tissue Adverse Reactions Update | Laura St. Martin, M.D. - FDA |

Transplantation Safety

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| 11:00 | Overview of WHA Resolution, WHA 63.22/ PAHO CD49.R18 | Malhi Cho, M.D. – PAHO, Washington DC |
| 11:20 | Overview of WHO Guidelines | Luc Noel, M.D. – WHO, Geneva Switzerland |
| 11:40 | Impact of Transplant Tourism in the U.S. | Francis Delmonico, M.D. – New England Organ Bank, Boston MA |
| 12:00 | CMS Conditions of Participation & Audits | Daniel Schwartz, M.D. - CMS Michel Walton, RN - CMS |
| 12:20 | Lunch | |
| 1:20 | Disease Transmissions Advisory Committee Role in Transplant Safety | Emily Blumberg, M.D., Hospital of the U. of Penn, Philadelphia, PA |
| 1:50 | OPTN Operations & Safety Committee: Methodology and Current Trends | Kimberly Taylor - UNOS |
| 2:10 | Open Public Comment | |
| 2:30 | Break | |
| 2:45 | General Committee Discussion | Committee |
| 5:00 | Adjournment | |

Wednesday, June 8, 2011

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| 08:00 | Doors Open | Open to the Public |
| 0:830 | Call to Order | Chairman |
| 08:35 | Roll Call Conflict of Interest | Jerry A. Holmberg, PhD Executive Secretary |

Patient Blood Management

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| 08:40 | WHA Resolution 63.12 – Overview of WHO Secretariat Report and WHA Resolution | Harvey Klein, M.D. - NIH |
| 09:10 | Patient Blood Management Performance Measures Project | Harriet Gammon, MSN, RN, CPHQ – The Joint Commission |
| 9:40 | Economics of Blood Transfusion | Axel Hofmann, M.E. – Medical Society for Blood Management, Austria |
| 10:15 | Break | |

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| 10:30 | Blood Component Utilization at the Hospital level: Guidelines, Education and Enforcement | Joseph Sweeney, M.D. – Roger Williams Hospital, Providence R.I. |
| 11:10 | Overview and Implementation of a Patient Blood Management Program | Irwin Gross M.D. – Eastern Main Medical Center, Bangor MA |
| 11:50 | Lunch | |
| 12:50 | Understanding the Past and Predicting the Future Of Blood Requirements | Richard Benjamin, M.D. – ARC Rockville MD |
| 1:30 | Red Cell Transfusion Management – Improving Patient Care and Safety Using Evidence Based Guidelines | Rana Samuel, M.D. – Department of Veterans Affairs Buffalo, NY |
| 2:15 | Break | |
| 2:30 | Open Public Comments | Chairman |
| 3:00 | Committee Discussion | Committee |
| 5:00 | Adjournment | Chairman |