

PPTA Approach to Pathogens

**HHS Advisory Committee on Blood Safety &
Availability
North Bethesda, Maryland
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PPTA Role in Pathogen Safety:

- Safety of individual therapies is a manufacturer responsibility
- Safety issues common to members are addressed by the Association
- Pathogen Safety Steering Committee
 - Global expert group on issues related to safety of plasma protein therapies
 - Science driven committee

Pathogen Safety Steering Committee:

- Identify and prioritize key safety issues
- Monitor, assess and comment on emerging pathogens
- Support liaison activities with authorities on scientific issues
- Initiate and monitor issue specific task forces

Recent Pathogen Safety Issues:

- Parvovirus B19
- West Nile Virus
- TSE Clearance/Sanitation Study
- Emerging Infectious Disease (EID)
Roundtable

EID Roundtable

- Venue: March 10-11, 2004, Brussels, Belgium

Objective: Provide forum for communication

- Regulatory policy makers
- Scientific experts
- Stakeholders

Topic: Strategies to assess threats to safety of plasma therapeutics from emerging infectious diseases

EID Roundtable 1

- **Format:**
 - Case Studies – vCJD, WNV, Parvovirus B19, SARS
 - Breakout Discussion Groups
- **Outcome:**
 - Continue to develop structure for communication coordination in face of EID
 - Develop pathway for “best practices” guide

Summary:

- PPTA coordinates industry-wide pathogen safety issues through steering committee activities
- PPTA sponsors EID Roundtable including industry, regulators and consumers to address response to future EIDs