Transfusion Related Acute Lung Injury (TRALI)

Leslie Holness, M.D.

Medical Officer, CBER,FDA

TRALI

FDA reports:

- **TRALI implicated in 10 - 14% of fatalities of the last three years**
- **Reactions :3, FY97, 12,FY 98, 17,99**
- **75% cases, donor products tested HLA /granulocyte antibody positive**

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Options for reducing morbidity & mortality

1. **Deferral of donors implicated in a single unit or in more than one multiple unit TRALI case.**

2. **Identify donors with risk factors followed by:**
   - **screen for HLA/granulocyte antibodies**
   - **deferral**
   - **diversion of plasma to non-injectables**

3. **Establishment of improved physician education about TRALI and improved surveillance mechanisms for donors implicated in non-fatal as well as fatal TRALI cases**

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- **Presentations:**

- **Dr. Mark Popovsky, President, Cell Processing Division & Corporate Medical Director, Haemonetics Corp. Associate Professor of Pathology , Harvard Medical School**

- **Dr. Patricia Kopko , Associate Director, Sacramento Medical Foundation Blood Centers, Assistant Clinical Professor, Medical Pathology, University of California, Davis**

- **Dr. Lynn K. Boshkov, Associate Professor and Director of Transfusion Medicine, Oregon Health Sciences University**

- **Dr. John Finlayson, Associate Director for Science, OBRR**

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- **Questions for the Committee:**

- **1. Should FDA consider interventions at this time to identify donors and/or donations with an increased risk for producing TRALI in a recipient?**

- **1a. If not, what data are needed to define appropriate measures**

TRALI

- **2. If yes (in 1.), would it be appropriate to identify blood donors with a history of :**
- **i. multiparity (3 or more pregnancies)**
- **ii. allogeneic transfusion**
- **iii. implication in a single unit case, or more one multiple unit TRALI case.**

TRALI

- **2b If yes (in 1.), for donors with risk factors (as in 2), would it be appropriate to:**
- **i. limit collections for transfusion to plasma reduced products(e.g. washed RBCs; apheresis platelets)**
- **ii. divert the plasma collections to the manufacture of non-injectable products**

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- **iii. screen for anti-HLA/granulocyte antibodies and permit negative donors to continue donating routinely**
- **iv. defer such donors**